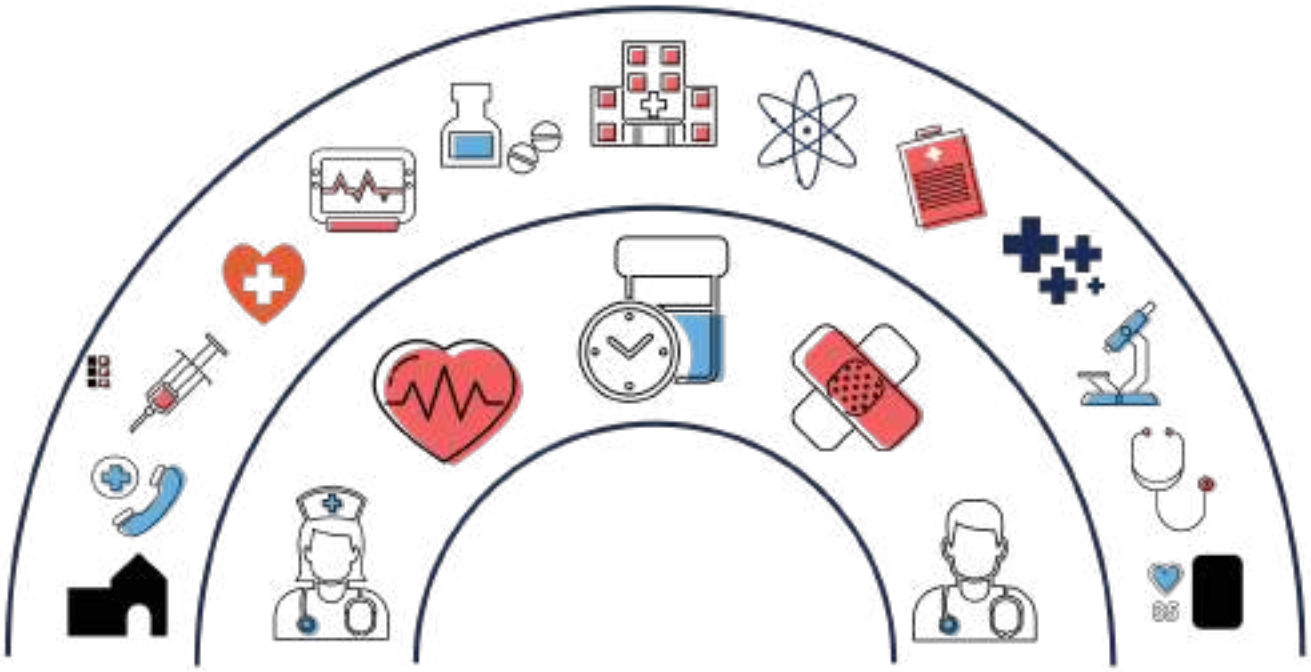
APRIL 2022



# BUILDING RESILIENCE IN INDIA'S POST-COVID HEALTHCARE SUPPLY CHAIN

GS1 India

ASSOCIATION OF HEALTHCARE PROVIDERS INDIA

# Foreword

The COVID-19 pandemic sent shock waves around the world, heightening human suffering and significantly impacting the health, economic, environmental and social fabric. The world has moved through uncharted territories, uncertain of the long-term and far-reaching impacts of the crisis. Two years into the pandemic, the world is still grappling with the continuous emergence of new challenges as novel variants emerge and healthcare systems struggle to respond.

The onset of the pandemic highlighted the challenges of our interconnected world as we observed the domino effect of the crisis on economies, trade, commerce and stock market, among other things. But more importantly, it revealed the global nature of supply chains and the interdependence of nations. As a result, there was a paradigm shift to strengthen global supply chains.

Pandemic induced lockdowns also exposed inconsistencies in public healthcare systems worldwide, to which India was no exception. India's healthcare system was shaken to its core when it faced unprecedented challenges of a complex and opaque supply chain leading to acute shortage of ventilators, non-availability of vital drugs, and logistics challenges of matching oxygen demand with supply.

While the healthcare supply chain challenges became starkly evident during COVID, the underlying factors making the healthcare supply chain vulnerable have been present for a long time, resulting in drug counterfeiting, pilferage, medication and billing errors, and a high level of wastage. These vulnerabilities compromise patient safety and increase the cost of healthcare delivery.

At the same time, hospitals bear the brunt of these supply chain challenges when it comes to forecasting demand, managing inventory, and ensuring effective recall of defective medical devices and expired medicines.

To address these challenges, we need to look no further than Indian pharmaceutical and medical device manufacturers who have successfully adopted global standards for the export market. It is time to implement these international best practices in the domestic market.

By creating end-to-end visibility in the healthcare supply chain through barcoding, master data management, and traceability solutions, we can dramatically improve patient safety and substantially reduce the cost of healthcare delivery in India.

Over the last two years, the pandemic has proved to be a catalyst for increased adoption of digital measures across Indian healthcare sector with the deployment of various technological solutions like the Co-WIN digital portal, Aarogya Setu app, and e-Sanjeevani OPD. The Government of India has launched the Ayushman Bharat Digital Mission (ABDM) to transform the current healthcare system into a 'patient-centric' one through a comprehensive digital stack.

Through the publication of 'Building Resilience in India's Post-COVID Healthcare Supply Chain', GS1 India, in collaboration with the Association of Healthcare Providers (India), sets out the current challenges facing the country's healthcare supply chain and outlines a roadmap to greater resilience in the years to come.

Firstly the report presents an overview of the healthcare sector in India including the policy paradigm. Second, it discusses the current status of India's healthcare supply chain and the resultant economic and patient safety costs. Third, the publication highlights the role of harmonised and interoperable standards for pharmaceutical products and medical devices to establish an effective track and trace system.

Next, critical learnings are brought out by reviewing global track and trace systems in the US, and the European Union.

Finally, the report puts forward practical solutions and implementation plans for building a resilient healthcare supply chain for a post-COVID world.

S. Swaminathan
Chief Executive Officer
GS1 India

Dr. Girdhar Gyani
Director General
Association of Healthcare Providers (India)

# About GS1 India

GS1 India (formerly EAN India) is a standards body set up in 1996 by the Ministry of Commerce and Industry and BIS, CII, FICCI, ASSOCHAM, FIEO, APEDA, IIP, IMC and Spices Board. GS1 India is affiliated to GS1, a global standards organisation headquartered in Brussels, Belgium, which oversees operations of GS1 member organisations in 115 countries.

GS1 standards are designed to improve the efficiency, safety and visibility of supply chains, including both physical and digital channels across 25 industry sectors, and form a business language that identifies, captures and shares critical information about products, locations, assets and more.

GS1 India provides guidance on the implementation of global standards to facilitate unique product identification, enabling interoperability, real-time stock management and faster and accurate billing at the point of sale.

In the healthcare sector, GS1 standards are extensively used to provide unique and universal identifiers for medicines and medical devices and are endorsed by the majority of global healthcare regulations.

The benefits of GS1 standards in Healthcare includes improved patient safety through the reduction in the risk of medication errors, improved clinical data records through accurate and automatic pick-up of treatment information, minimizing waste through better stock management and providing the framework for building traceability systems to automatically record batch/lot information.

In 2011, DGFT had mandated incorporation of barcodes with GS1 identification standards for medicines for export from track & trace and authentication perspective. At the same time, several divisions under the Ministry of Health & Family Welfare and various State Government Health Departments use GS1 standards for procurement of pharmaceuticals to facilitate track and trace, expiry and inventory management, detection of spurious drugs through authentication and product recalls. Also, the Insurance Information Bureau (under IRDAI) makes use of GS1 standards for unique hospital identification for insurance claims under the 'ROHINI' project.

# About Association of Healthcare Providers (India)

Association of Healthcare Providers (India) represents the vast majority of healthcare providers in India. It was registered under Society Registration Act- 1860 as “not for profit” organization in December 2012. It educates its members and at the same time, advocates with the government, regulatory bodies and other stakeholders on issues, which have bearing on enabling its member organizations in delivering of Universal Health Coverage to the community at large.

AHPI is administered by Governing Body, which comprises of eight founding members i.e., Dr Devi Shetty, Dr Prem Nair, Dr Rajasekar, Dr Bhabatos Biswas, Dr Alex Thomas, Dr N Trivedi, Dr Soma Raju & Dr Girdhar Gyani. In order to engage with hospitals effectively, there are 19 State/regional chapters covering entire India, with each chapter having its President, Secretary and members as part of State Executive Committee. Presidents of regional chapters are also part of Governing Body. This makes AHPI as true pan India representative body.

In academics, AHPI has contributed through number of publications and papers. It has developed standards on patient safety, green & clean hospitals, ICUs, patient friendly hospitals etc. It has contributed through publication of two books on ‘Healthcare Quality & Patient Safety’ and ‘Healthcare Communication’, which are used as reference material for PG courses in NBE. AHPI is working as an umbrella organization in supporting entire family of healthcare providers with motto: ‘Educating & Advocating for Well Being of Common Man’.

# Message

It's a pleasure to write a message for this well researched and rigorous report. As we know, the COVID-19 pandemic has tested the resiliency of the Indian healthcare supply chain. It has stretched it to its limit and identified the areas of possible improvement.

One of the primary challenges faced by the patients and healthcare stakeholders is the ability to distinguish between the genuine and fake drugs and devices. This is majorly because counterfeit drugs and devices percolate in the supply chain through various means, posing grave threat to patient health and safety. Hence, it is of paramount importance to tackle this issue.

To tackle the same, government, healthcare industry, regulators and subject matter experts, must come together to implement interoperable mechanisms, enhancing patient safety through the authentication and expiry management of drugs and devices, and reducing errors by providing complete visibility and transparency throughout the supply chain. This will also help in better inventory management and waste reduction, making healthcare affordable and accessible to all.

This report aims to do just that. GS1 India, a global standards body and AHPI, a voice of healthcare providers in India, have come together to flesh out essential insights from key industry stakeholders and lay out a roadmap for building a resilient and future ready supply chain.

I encourage you to have a look at the report and go through the recommendations.

Dr. Devi Prasad Shetty
Chairman and Executive Director
Narayana Health

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# Executive Summary

India's healthcare sector has been growing at a brisk pace, becoming one of the largest sectors, both in terms of revenue and employment. The sector is further expected to grow in the coming years, with the government focusing its attention on increasing its public health expenditure to 2.5% of GDP by 2025 as a part of the National Health Policy 2017.

The different segments making up the healthcare sector in India are hospitals, pharmaceutical manufacturers, medical device manufacturers, retail and e-pharmacies. The report highlights the current market size of each of these segments and their predicted growth trajectory by 2030. By and large, these segments are estimated to reach a substantial market size growing in double digits.

The size and growth of the healthcare industry can be attributed to the emerging key trends and growth drivers. An ageing population along with a growing middle-class, a rise in telemedicine channel, an increase in awareness amongst consumers regarding their health, and an expanding medical tourism base are all set to contribute to the sector's growth.

Additionally, India's health policy paradigm is driving the industry's growth.

The government plays a pivotal role in advancing the sector by introducing various schemes and policies that would benefit the citizens. The Ayushman Bharat scheme is one such initiative by the government and is dealt with in great detail in the upcoming sections.

However, the healthcare sector is facing numerous hurdles that hinder its growth. This report focuses on one such issue, an inadequate healthcare supply chain in chapter two. India's healthcare supply chain faces five key challenges: fragmentation, complexity, opaqueness, lack of agility and inefficiency. Furthermore, the economic and patient safety cost that result from counterfeiting, pilferage and product recall is also discussed and supplemented with insights gathered through our primary research with industry stakeholders.

Chapter three focuses on solving the identified problems in the healthcare supply chain, through the use of global standards which provide a common language and a benchmark for all parties operating in the supply chain. Implementing global standards into the current supply chain has numerous benefits ranging from product tracking, tracing, and recall to enabling reliable and accurate product information exchange.

In addition, it drastically improves supply chain visibility and reduces the menace of counterfeit products.

Global standards can be implemented in the form of a unique identification key that is barcoded on the outer packing of pharmaceutical products and medical devices. The two most commonly available two-dimensional keys are the GS1 DataMatrix and the Quick Response (QR) code. This chapter also highlights the merits of GS1 DataMatrix over linear barcodes and Quick Response (QR) codes.

The fourth chapter focuses on the international implementation of global standards. Track and trace systems are of two types: Point-of-dispensing check and full track and trace systems. The two systems vary in many aspects but most importantly, the point-of-dispensing check system checks for the authentication of pharmaceutical products at the end point-of-sale. In contrast, a full track and trace system covers all aspects of supply chain visibility at all distribution levels.

The United States of America and the European Union are examples of nations and regions implementing traceability standards into their healthcare supply chain. Both of these cases are discussed, and the benefits accrued from implementing such systems are also highlighted. The learnings from both of these cases are a good starting point for India to adopt traceability measures in the domestic supply chain. In addition, the case studies shed light on the gradual implementation process undertaken by the regulatory authorities and how each country approached differently to make the healthcare supply chain resilient.

The fifth and the last chapter lays down a set of recommendations for the three key stakeholders in the healthcare sector: Government, Regulators, and the Industry to build a future-proof supply chain that is transparent makes data visible, and allows track and trace.

The government plays a central role in leading the way forward because of the many resources at its disposal and its ability to implement programmes through its patient-centric initiatives and policies to improve patient safety.

First, the government can ensure that the discipline of 'patient-safety' holds central importance. Second, it needs to develop a robust technological infrastructure to complement the traceability measures. And finally, it can help MSMEs implement traceability measures by providing concessions and training support.

While the government can sanction policies and release notifications to lay the foundations of a track and trace system, the regulatory bodies need to ensure the implementation of government directives based on their area of expertise and impart learnings from previous experiences in rolling out an end-to-end visibility system. The regulators need to start from the source i.e. at the point of manufacturing the products to implement global standards, engage with all stakeholders from the beginning, approach supply chain visibility in a phased manner and implement uniform barcoding standards.

The third group of stakeholders, which consists of the industry players, can ensure that the directives from the government and regulatory authorities are implemented into the system at the micro-level. The industry needs to shift its focus from the costs that will be incurred in the implementation of such traceability measures to the benefits that it will accrue. This is also one of the benefits. Finally, they need to be equipped technologically to garner the maximum benefits from global standards.

# INDIA'S HEALTHCARE SECTOR - A CRITICAL PILLAR OF WELL-BEING OF CITIZENS AND ECONOMIC GROWTH

Building Resilience in India's post-COVID
Healthcare Supply Chain

India's healthcare industry comprises of producers, providers and payers. Producers are companies manufacturing pharmaceutical products and medical devices, whereas providers offer healthcare services to citizens either on-site or remotely. These include hospitals, clinics, diagnostic labs and pharmacies. Finally, payers pay for the treatment received by the patients. These include government and private insurance and the patient paying herself through out-of-pocket.

India's healthcare sector has witnessed rapid growth over the last five years, exhibiting a compounded annual growth rate of 16% since 2016.[1] The industry will reach a market size of US$ 877 billion (₹65 lakh crores) by 2030 if it continues to grow at the same pace.[2]As a result of the rapid and sustained growth, the sector augmented jobs and economic development, directly employing 4.7 million people.[3]

EXHIBIT 1

## India's healthcare sector comprises producers, providers and payers


### Pharmaceuticals
- Discovering, manufacturing and marketing chemical materials to be used as medications.

### Medical Devices
- Primarily manufacturing medical equipment and supplies.

### Hospitals & Clinics
- Government healthcare institutions and private health facilities providing patient treatments onsite or through telemedicine.

### Diagnostics
- Comprises of businesses & laboratories that offer analytical or diagnostic services.

### Pharmacies
- A shop or hospital dispensary where medicinal drugs are prepared or sold including unorganised chemist shops, organised pharmacy chains and e-pharmacies.

### Health insurance
- Insurance that covers an individual's hospitalisation expenses incurred due to sickness, includes both government insurance schemes and private insurers.

### Out of pocket
- Expenses that aren't reimbursed by insurance and are paid by the patients out of their pockets.

[1] Indian Healthcare Industry Analysis, India Brand Equity Foundation
[2] India Brand Equity Foundation, Techsciresearch, Statista
[3] Investment opportunities in India's healthcare sector, NITI Aayog

There is a well-established correlation between citizens' health and the nation's economic growth. A study by the WHO on 'Health, Economic Growth and Poverty Reduction' pointed out that a mere 10% increase in life expectancy ensures an economic growth of 0.4% per annum[4]. A healthy citizen is seen as an asset because his/her productivity adds to reduced production losses due to illness and lower absenteeism rates.

Healthcare is one of the most vital factors that transform the stock of human resources into human capital, ensuring a significant contribution by each citizen to economic prosperity.

There has been an apparent shift in the government's focus on the required infrastructure to aid the growth of the healthcare sector by increasing India's public health expenditure as a percentage of GDP to 1.8% in FY 2020-21[5][6], compared to 1.2% in FY 2014-15. Further, the government is committed to increasing its public health expenditure to 2.5% of GDP by 2025 as a part of the National Health Policy 2017.[7] However, India's targets are still lower than BRICS nations: Brazil spent the most (9.2%), followed by South Africa (8.1%), Russia (5.3%), and China (5%).[8] In contrast, the OECD countries spent an estimated 8.8% of their GDP on healthcare expenditure in 2018 with developed nations like the USA (16.9%), Germany (11.2%), France (11.2%) and Japan (10.9%) spending even more.[9][10]

# The size and growth of the healthcare sector

India's pharmaceutical industry is home to more than 3,000 companies with a strong network of over 10,500 manufacturing facilities.[11] It offers 60,000 generic brands across 60 therapeutic categories.[12] Accredited as the 'generic pharmacy of the world', India's booming pharmaceutical industry, accounts for 20% of the global exports in generics, standing at US$ 24.44 billion[13] (₹1.8 lakh crores) in FY21 and serving more than 200 destinations.[14] The industry is estimated to reach a market size of US$ 130 billion (₹9.6 lakh crores) by 2030 from the market size of US$ 42 billion (₹3.1 lakh crores) in 2021, growing at a compounded annual growth rate (CAGR) of 13%.[15]

The medical devices and equipment segment includes five categories: Consumables & Disposables, Diagnostic Imaging, Dental Products, Orthopaedics & Prosthetics and Patient Aids.

Devices grew significantly over the past decade to a market size of US$ 12 billion (₹89,000 crores) in 2021;[16] however, a substantial demand-supply gap remains. There are 750-800 medical device manufacturers in India, with 65% operating in the consumables segment catering to the domestic demand with limited exports.[17] It is expected to reach a size of US$ 63 billion (₹4.6 lakh crores) in 2030, growing at a CAGR of 20%.[18]

The hospital segment had a market size of US$ 67 billion (₹4.9 lakh crores) in 2021.[19] With a constantly expanding array of investment opportunities available in this segment, especially in Tier 2 and Tier 3 locations, the hospital market is estimated to reach a size of US$ 137 billion (₹10.1 lakh crores) by 2030; growing at a CAGR of 8% with the private players playing a pivotal role in achieving the same.[20]

[4] Health, Economic, Growth and Poverty Reduction, WHO
[5] Investment opportunities in India's healthcare sector, NITI Aayog
[6] ibid.
[7] National Health Policy 2017
[8] India's economy needs big dose of health spending, Livemint
[9] ibid.
[10] ibid.
[11] Indian pharmaceutical industry, India Brand Equity Foundation
[12] Pharmaceuticals, India Brand Equity Foundation
[13] Indian pharmaceutical industry, India Brand Equity Foundation
[14] Annual Report 2021, Pharmexcil
[15] Pharmaceuticals, India Brand Equity Foundation
[16] India Brand Equity Foundation, WHO

The government is increasingly focusing on public-private partnership (PPP) models to augment growth in the hospital segment.

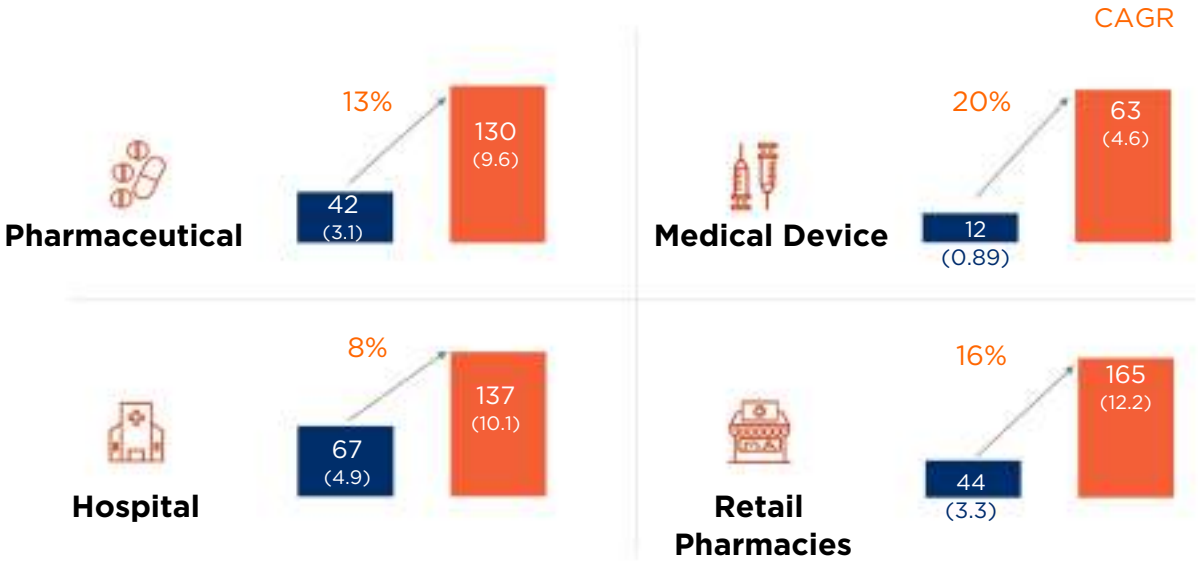
The retail pharmacies in India have grown at a fast pace, with market size of US$ 44 billion (₹3.3 lakh crores) in 2021, projected to reach US$ 165 billion (₹12.2 lakh crores) by 2030. [21]

While current pharma retail is highly fragmented, it's slowly progressing towards an organised retail format. Apollo Pharmacy, Emami Frank, MedPlus Health, RWL Healthworld and the Himalaya Drug Company dominate organised retail in India.

EXHIBIT 2

## India's healthcare sector is projected to grow in double digits to 2030

**Market Size & Growth in Healthcare sub-sectors In USD Billion (Lakh Crore Rupees)**




Note: Pharmaceutical and medical devices market size is for domestic and export market.
Source: India Brand Equity Foundation, TechSci Research, Statista

[17] Medical devices, Invest India
[18] Medical Device Manufacturing in India - A Sunrise, WHO
[19] India Hospital Market, Techsciresearch
[20] India Hospital Market, Techsciresearch
[21] India Retail Pharma Market Size, Statista

The arrival of e-pharmacies since 2015 has added a unique dynamic to the healthcare supply chain and disrupted retail pharmacies simultaneously. At present, there are 50 e-pharmacies operating in India, with a market estimate of US$ 0.7 billion (₹5,300 crores) in 2020, making up approximately 1.6% of the total domestic pharmacy sales.[22] Pharmeasy, Medlife, 1mg, Netmeds and Sastasundar are some of the leading e-pharmacy players vying for a share of this market.

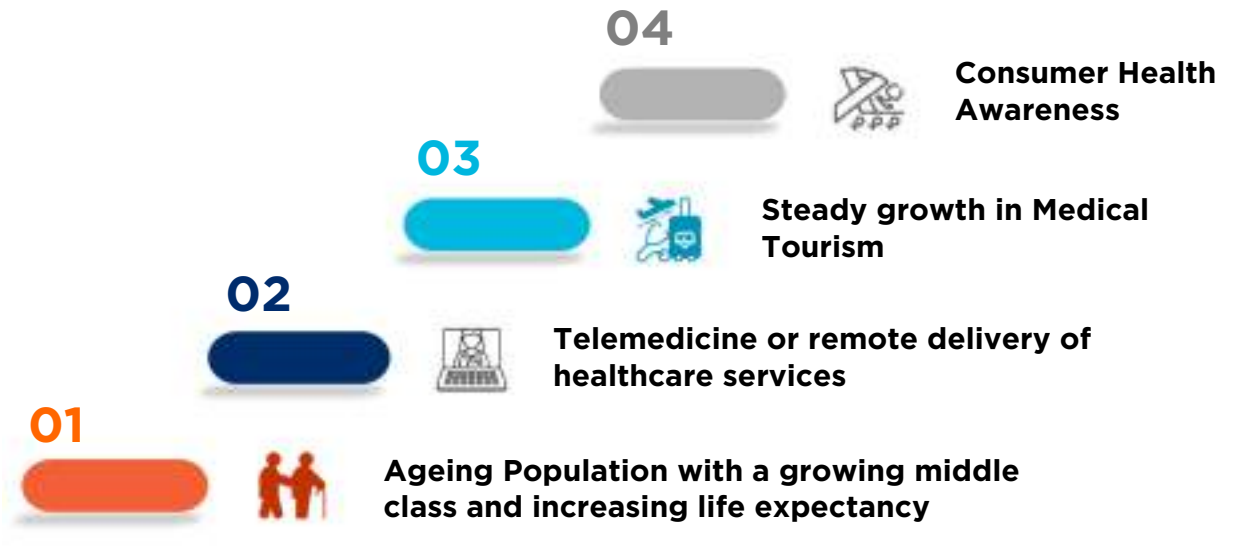
The rise of e-pharmacies as a critical retailer in the distribution network is due to a change in consumer preferences favouring e-commerce adoption, accelerated further post-COVID. Furthermore, the growth momentum will be supplemented by the number of internet users expected to grow at a compounded rate of 8.8% between 2020-2025.[23]

## Key trends and growth drivers

The healthcare industry in India is experiencing four key trends that will drive its growth and shape the delivery of services for a large and changing population base.

EXHIBIT 3

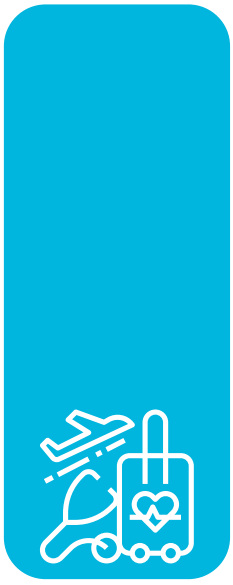
### Indian healthcare industry is experiencing four key trends and growth drivers




[22] e-Parmacies - Bridging gap Indian Healthcare, Invest India
[23] e-Pharmacy in India is winning the battle over traditional medicines, India Brand Equity Foundation

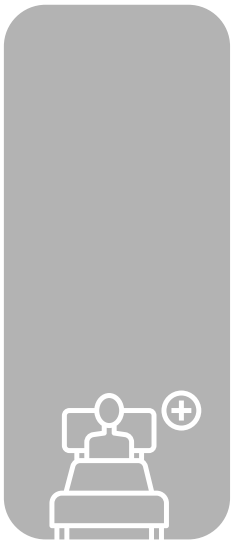
An ageing population with a growing middle class and higher life expectancy will boost India's demand for healthcare services that increasingly favour wellness and preventive services. Improved life expectancy rates have led to a demographic shift in citizens above 65 years of age. With a rapidly growing elderly population, healthcare infrastructure must improve for their betterment. And rising income levels will result in an increased middle-class category of households, thereby enhancing their purchasing power, including healthcare.

Another trend gaining traction is the remote delivery of healthcare services over telecommunication channels. Telemedicine established its foundation at the outbreak of the COVID-19 pandemic and the subsequent enforcement of social distancing norms which posed a challenge for the citizens to get access to medical advice. Consequently, the government released the Telemedicine Practice Guidelines in March 2020 alongside teleconsultation services, namely e-Sanjeevani and e-Sanjeevani OPD, to enable diagnosis, treatment and management of diseases. Moreover, leading telemedicine start-ups such as Practo, 1mg, mFine, iCliniq, and myUpchar reported an upsurge in doctor consultations by 4-9 times between March and June 2020, with close to 80% first-time users on these platforms.[24]



Medical tourism grew steadily over the past few years until the imposition of abrupt lockdowns and cancellation of flights in response to the COVID-19 crisis. As a result, over 6% of the total tourist inflow to India was for medical purposes in 2018 and 2019.[25] However, hospitals that usually hosted 10-15% of their patients from overseas recorded a negative growth last year because of the pandemic. Still, India remains a preferred destination for medical travel because of the availability of affordable healthcare options, highly specialised doctors and health personnel and the presence of world-class hospital facilities coupled with increased investment into healthcare infrastructure.

Furthermore, the Ministry of Tourism has constituted a Wellness and Medical Tourism Promotion Committee (WMTPC) and formulated detailed guidelines to promote wellness and rejuvenation, medical treatment and alternative medicine as niche tourism products among international tourists. For these reasons, a rising trend is likely to occur, with the Trade Promotion Council of India (TPCI) reporting the medical tourism segment to value US$ 13 billion (₹96 thousand crores) by 2022.[26]



Consumer health awareness is another trend driving the growth of the healthcare market. Indian consumers have become more conscious of their healthcare needs due to advancing literacy rates, increasing purchasing power and the easy availability of credible medical content through digital channels.[27] This change in consumer behaviour is well-supported by increasing internet penetration and the democratisation of the telecom sector. Smartphone penetration in rural India has risen from 9% in 2015 to 25% in 2018,[28] and the number of active internet users in India will increase by 45% in the next five years, touching 90 crores by 2025,[29] driving an uptick in the inclination of consumers towards health data management.

Furthermore, due to the COVID-19 outbreak, Indian consumers have witnessed a dramatic shift in their ability to access healthcare products and services with demands for more information about the products they consume. A recent study, 'Life in a Pandemic', stated that around 80% of the respondents reported improving their eating habits, and 33% performed some form of physical activity to maintain their overall fitness and health.

[24] Towards a telehealth ecosystem, Fortune India
[25] Medical tourism to India on the up as Covid impact ebbs, Hindustan Times
[26] Medical Value Tourism: Time to Heal in India, Trade Promotion Council of India
[27] 3 reasons why consumer healthcare in India is set to take-off, World economic Forum
[28] India to have 900 million active internet users by 2025, Economic Times
[29] Life in a pandemic, EY

# India's healthcare policy paradigm

The role of the Indian government has been instrumental in transforming the healthcare sector over the last few decades. It has successfully filled a significant vacuum in the infrastructure needed for a healthy population. Registry of Hospitals in Network of Insurance (ROHINI) is one such initiative by the government to create benefits for health insurance stakeholders by preventing insurance frauds on account of fake hospital information. In addition, it serves as a single source of reliable, updated and authenticated information on the location of a hospital and medical day-care centre offering cashless insurance.

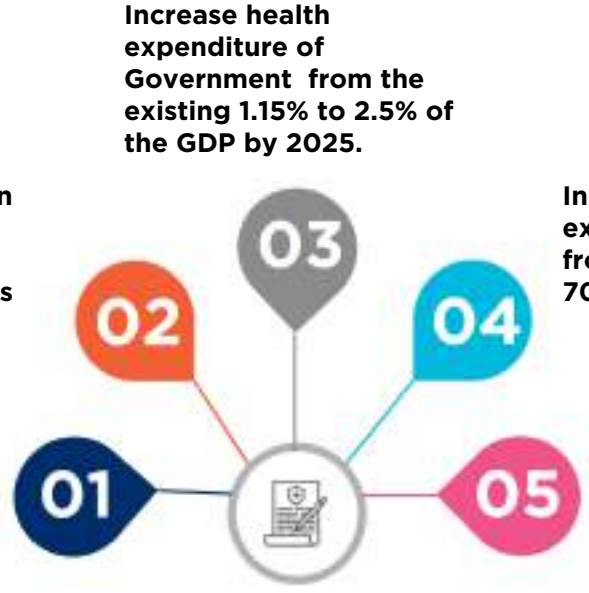
Similarly, the Ayushman Bharat Yojana aims to undertake pathbreaking interventions to holistically address the healthcare system at the primary, secondary and tertiary levels. At the same time, Pradhan Mantri Jan Aushadhi Yojana makes quality medicines available at an affordable price for people, particularly the poor and disadvantaged, through exclusive outlets "Jan Aushadhi Medical Stores".

In addition, Ayushman Bharat Digital Mission (ABDM) aims to create a platform to store and exchange citizens' health records. However, with changes in the global health scenario and the needs of an ever-changing population, a great deal remains to be done.

The earlier National Health Policies (NHP) in 1983 and 2002 had served their motives of achieving an acceptable healthcare standard for the Indian population and making the nation self-reliant in terms of healthcare infrastructure. Against this backdrop, the government formulated National Health Policy 2017 to improve the national health scenario substantially. Under the NHP 2017 framework, India will achieve Universal Health Coverage by 2025 without any citizen having to face financial hardship as a consequence.

EXHIBIT 4

## India's National Health Policy 2017 has set five key goals




**01** Decrease in proportion of households facing catastrophic health expenditure from the current levels by 25%, by 2025.

**02** Increase utilisation of public health facilities by 50% from current levels by 2025.

**03** Increase health expenditure of Government from the existing 1.15% to 2.5% of the GDP by 2025.

**04** Increase life expectancy at birth from 67.5 years to 70 years by 2025.

**05** Reduction of Total Fertility Rate (TFR) to 2.1 at national and sub-national level by 2025.

Source: National Health Portol of India

The most critical programmes proposed by the policy are the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (PM-JAY) and the Ayushman Bharat Digital Mission (ABDM).

Ayushman Bharat scheme adopts a consistent care approach comprising two inter-related components: Health and Wellness Centres (HWCs) and the National Health Protection Scheme (PM-JAY).

Under its first component, the government aims to set up 1,50,000 Health and Wellness Centres (HWCs) by 2022 to deliver comprehensive primary healthcare ranging from maternal and child health care services to non-communicable diseases, palliative and rehabilitative care.[30] India had crossed a key milestone in universal primary healthcare on 21st March 2021 when it achieved the target of operating 70,000 HWCs ahead of time.[31]

The second component, the Pradhan Mantri Jan Arogya Yojana (PM-JAY), is the world's largest government-funded health insurance scheme. It provides a health cover of Rs. 5 lakh per family per annum for secondary and tertiary care hospitalisation across India's public and private empanelled hospitals. PM-JAY envisions to help mitigate catastrophic expenditure on medical treatment, which pushes nearly six crore Indians into poverty each year. There were 16.51 crore Ayushman Bharat cards as of eleventh October 2021, benefitting 2.18 crore hospitalised beneficiaries. [32]

EXHIBIT: 5

## Ayushman Bharat Scheme comprises of two inter-related components

Ayushman Bharat was launched in 2017 by the recommendation of National Health Policy to achieve the vision of Universal Health Coverage (UHC). Ayushman Bharat adopts a continuum of care approach, comprising of two inter-related components.

### HEALTH AND WELLNESS CENTRES (HWCs)

- The goal of HWCs is to achieve Universal Health Coverage with the creation of 1,50,000 HWCs, bringing healthcare closer to people.
- These centers will provide Comprehensive Primary Health Care (CPHC), covering both maternal & child health services and non-communicable diseases, including free essential drugs and diagnostic services.

### PRADHAN MANTRI JAN AROGYA YOJANA (PM-JAY)

- PM-JAY aims to provide health protection cover to poor and vulnerable families against financial risk arising out of catastrophic health episodes.
- It will cover medical & hospitalization expenses for almost all secondary care and most of tertiary care procedures of up to 5,00,000/- per family per annum.
- There will be no cap on family size and age to ensure maximum benefits.

Source: PMJAY.gov.in

[30] Ayushman Bharat – Health and Wellness Centres
[31] ibid.
[32] National Health Authority

The other important programme is the Ayushman Bharat Digital Mission (ABDM), which aims to make the health sector in India more technologically advanced, inclusive, and delivery-driven.

The government plans to holistically approach national healthcare by leveraging information technology and associated services while supporting the existing health system in a 'citizen-centric' manner.

EXHIBIT 6

## Ayushman Bharat Digital Mission consists of four key components

### MISSION

The Ayushman Bharat Digital Mission (ABDM) aims to develop the backbone necessary to support the integrated digital health infrastructure of the country. It will bridge the existing gap amongst different stakeholders of the healthcare ecosystem through digital highways.

### VISION

ABDM shall create a seamless online platform "through the provision of a wide range of data, information and infrastructure services, duly leveraging open, interoperable, standards-based digital systems" while ensuring the security, confidentiality, and privacy of health-related personal information.

### COMPONENTS


Source: Ayushman Bharat Digital Mission

The ABDM promises the integration of every individual's healthcare history with a unique 14-digit health ID. In addition, patients' Electronic Health Records will be stored digitally with the healthcare service provider, who can share them with other providers with a patient's due consent. To facilitate ABDM, the government has rolled out a digital platform, the Unified Health Interface (UHI).

The platform hosts a variety of health services, including teleconsultation and the booking of laboratory tests, heralding a giant leap towards digitisation and health data management in the coming years.

# CURRENT STATUS OF INDIA'S PHARMA AND MEDICAL DEVICES SUPPLY CHAIN

# Healthcare Supply Chain in India

At the centre of India's healthcare sector is a multi-step supply chain that ensures the delivery of drugs and devices to patients in hospitals and homes. Supply chain management is crucial for any organisation, helping them lower expenses, increase sales, and improve responsiveness. However, in the case of the healthcare sector, it becomes critical because of the importance of saving a human life beyond just managing costs and growing revenue.

The pharmaceutical supply chain starts with the production of raw materials, generally categorised into three constituents which form the inbound logistics of the drug manufacturer:

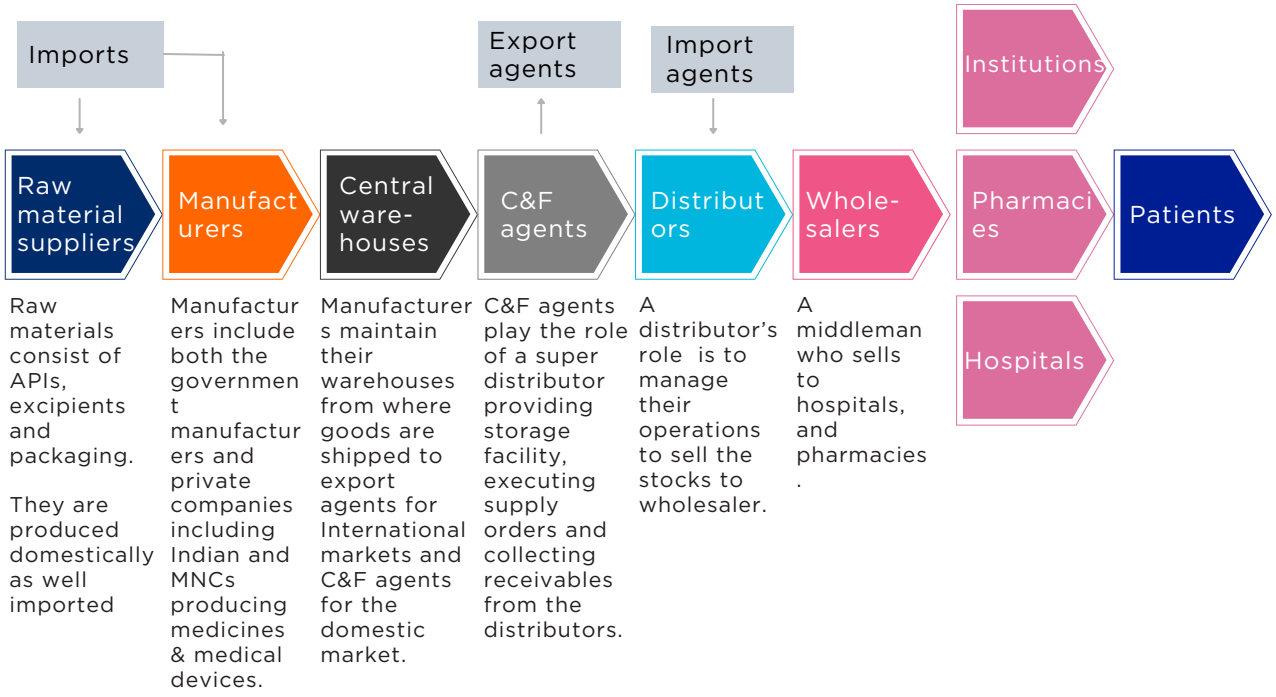
- Active Pharmaceutical Ingredients (APIs), the part of the drug, is pharmaceutically active and is responsible for the drug action.
- Excipients are also called inactive ingredients or drug carriers of solvents and other such carriers. Excipients bring bulkiness and stability in the drug formulation, facilitate absorption and prevent denaturation of drugs.
- Packaging includes diversified raw materials, including plastics, glass, aluminium foil, and paper.

Clearing and forwarding agents (C&F) are part of the distribution chain and are primarily responsible for maintaining a stock of the company's products and forwarding SKUs to the distributors on request. A distributor can handle more than one company and sells products to the wholesaler. Finally, they will pass the drug onto pharmacies, hospitals, and institutions to reach consumers (patients).

Drug manufacturers combine raw materials into the required proportions to manufacture drugs for healthcare providers and patients. Manufacturers maintain their warehouses to store products from where they are shipped to export agents for international markets and clearing and forwarding agents for the domestic market.

EXHIBIT 7

## Medicines and medical devices pass through multiple stakeholders to reach patients




Source: Competition Commission of India

While the medical devices supply chain also follows a similar structure to reach patients, it is highly dependent on imports, making up 75-80% of India's total market demand.[33] On the other hand, the pharmaceutical industry is export-oriented, with 58% of its total sales generated from exports.[34]

An adequate supply chain helps fulfil demand by providing the right product at the right price to the right person. The critical elements of a well-managed supply chain include:

- Ensuring a continuous supply of drugs
- Protecting from counterfeits
- Minimising loss due to expiration and damage
- Administering the correct dose to the right patient
- Making recall easy and cost-effective
- Maintaining medicines and devices in good condition
- Capturing information to support demand forecasting
- Maintaining optimum inventory levels
- Achieving efficiency in transportation

EXHIBIT 8

## A well-managed supply chain includes nine key elements


Organisations match their supply with the demand by effective forecasting, proper sourcing, timely production, and efficient storage and distribution by managing and monitoring inventory at various stock points.

The COVID-19 pandemic highlighted the inadequacy of the healthcare supply chain for a population of 135 crore people in India. At the peak of the first and second waves of the pandemic, the country faced extreme difficulties in arranging hospital beds and procuring Remdesivir injections and Oxygen cylinders for COVID patients.

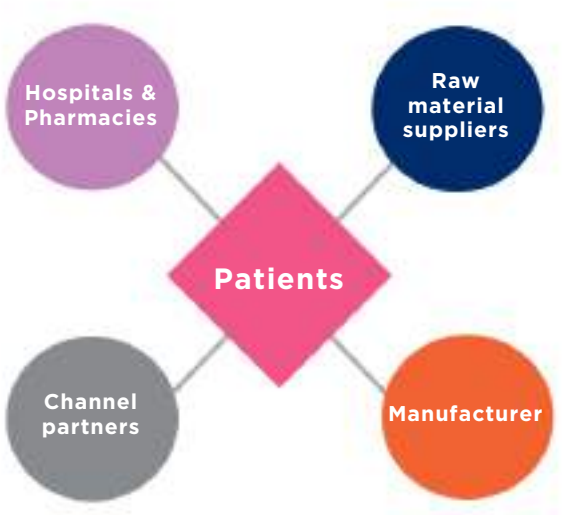
Despite the government's concerted efforts to make such crucial life-saving drugs and medical devices available to the public, there were incidents of selling Remdesivir injections and Oxygen cylinders at exorbitant prices in the black market. The large scale unavailability of beds, essential medicines and oxygen cylinders wreaked havoc on the nation, endangering patient safety, creating an urgency for improving transparency and visibility in the healthcare supply chain.

[33] India can ramp up export of medical devices amid customer diversification away from china, Financial Express
[34] Pharmaceuticals, India Brand Equity Foundation

EXHIBIT 9

## Healthcare industry stakeholders face multiple challenges in managing end to end supply chain

- Counterfeit products
- Product recall
- Medication errors
- Lack of skilled personnel
- Inadequate inventory management
- Dependency on manual processes




- Heavily import dependent
- Lack of technological advancements for production
- Geographically scattered over long distances
- Lack of infrastructure for transportation like cold chain storage facility

- Inadequate inventory management systems
- Product recall
- Lack of visibility in the supply chain
- High fragmentation due to a large number of players

- Lack of barcode labelling
- Brand Protection
- Drug counterfeiting
- High installation costs of traceability system
- Inadequate technological infrastructure
- Limited supply chain visibility
- Lack of interoperability

Source: Competition Commission of India

## Current challenges of India's healthcare supply chain

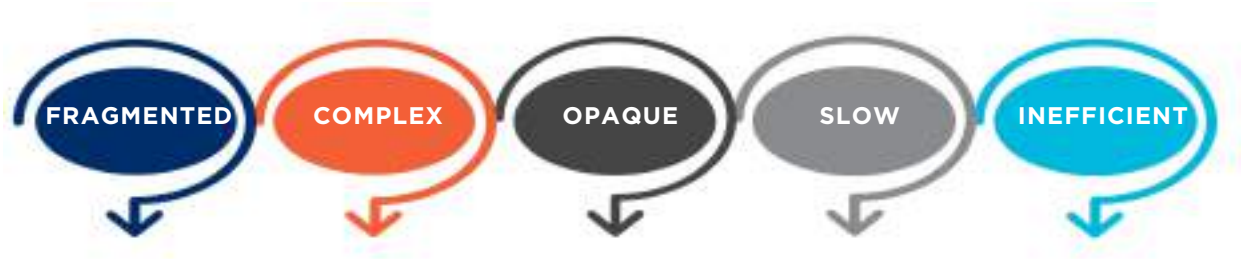
While COVID-19 was a wake-up call to build a resilient supply chain, managing the healthcare supply chain has been far from desirable in ensuring low cost and time availability of drugs. This underperformance is because of several structural and country-specific issues despite India's position as 'the world's pharmacy'.

These include many players at every stage of the supply chain, small sized manufacturers and hospitals, unorganised chemists, vast geographic areas and a lack of data and technology used to manage the storage and movement of products.

EXHIBIT 10

# India's healthcare supply chain is fragmented, complex, opaque, slow and inefficient

## Five challenges facing healthcare supply chain in India




| FRAGMENTED | COMPLEX | OPAQUE | SLOW | INEFFICIENT |
|---|---|---|---|---|
| Presence of thousands of players at each step of the supply chain from manufacturers to chemists | Increasing complexity due product proliferation, varying regulations and complex distribution structure | Limited and manual data capture, lack of data sharing with supply chain partners | Longer inventory holding period as a result of multiple storage points and lack of stock visibility | Higher costs of supply chain compared to global counterparts |

Firstly, the pharmaceutical supply chain in India is highly fragmented due to the many players and distribution levels involved. For example, there are around 9 lakh private retail chemists operating alongside 65,000 pharmaceutical distributors in India.[35] Such a fragmented supply chain tends to jeopardise the quality and safety of pharmaceutical products since it increases the number of entry points for counterfeit medicines.

On the other hand, India is highly dependent on imports for medical devices, requiring a high performing distribution network. Furthermore, as most players operate in the core metropolitan areas and tier 1 and tier 2 cities, with a limited pan India coverage, medical device manufacturers appoint many supply chain partners, adding to the supply chain fragmentation.

[35] Market Study on the Pharmaceutical Sector in India, Competition Commission of India

EXHIBIT 11

# Healthcare supply chain is highly fragmented with thousands of materials and players required to deliver drugs and devices to the patient

| 15,000+ | 10,000+ | 200+ | 65,000+ | 9 Lac | 135+ cr |
|---|---|---|---|---|---|
| Raw materials are managed by companies | Facilities are clustered around special economic zones in five to six states | Destinations to which exports go to | Distributors are available | Number of pharmacies | Number of citizens |

Source: Organisation of Pharmaceutical Producers of India, India Brand Equity Foundation, Competition Commission of India

Second, the supply chain is also complex, stemming from numerous reasons. For example, as companies constantly expand their product portfolio to meet the changing market demands, they need to keep track of the ever-increasing number of stock-keeping units (SKUs), putting pressure on an overstretched inventory management system.

A lack of a uniform regulatory framework for exports and domestic consumption is another cause for the complexity in the supply chain. Manufacturers follow export requirements due to stringent directives from importing countries, cherry picking in domestic market is not available to manufacturers. Following different market norms adds to manufacturers' costs and prevents interoperability.

Large pharmaceutical companies operate their production from eight to ten geographically scattered locations, and transportation of pharmaceutical products requires robust infrastructural support.

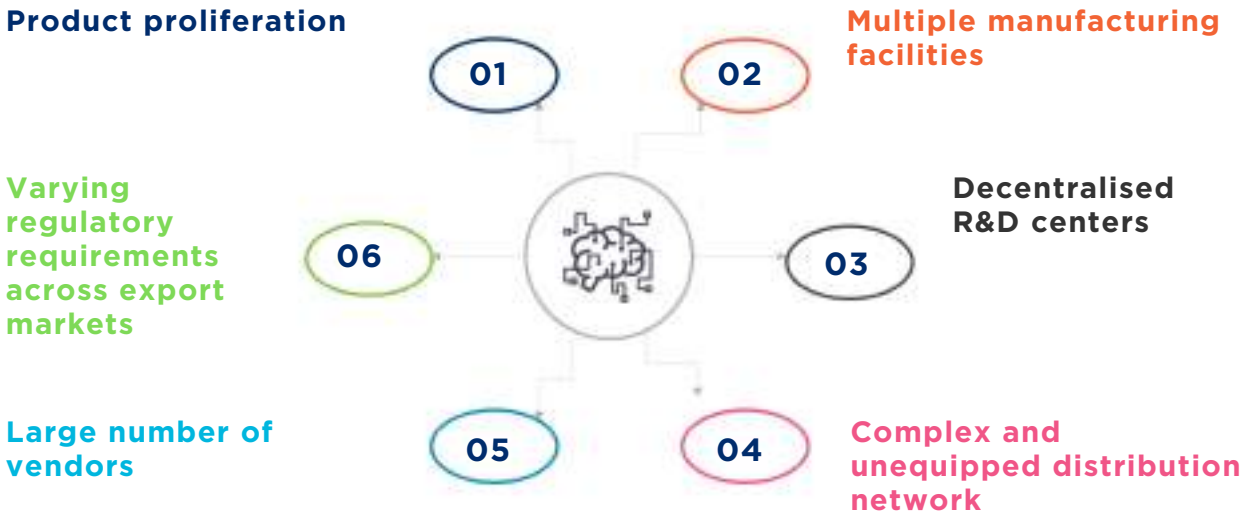
However, the present distribution network lacks basic infrastructure like cold-chain logistics, temperature control systems and database systems for safe and efficient delivery of drugs.

Companies also use multiple in-house R&D centres or third-party R&D centres at different stages of drug development. This creates complexity in transferring technology and lengthening timelines for regulatory approval. A complex and unequipped distribution network in the pharmaceutical supply chain further adds to the complexity.

In the case of medical devices, the high dependence on imports requires manufacturers and distributors to deal with varying regulatory requirements from the exporting countries.

EXHIBIT 12

## Six factors from product proliferation to unequipped distribution network make the supply chain complex




Source: Organisation of Pharmaceutical Producers of India

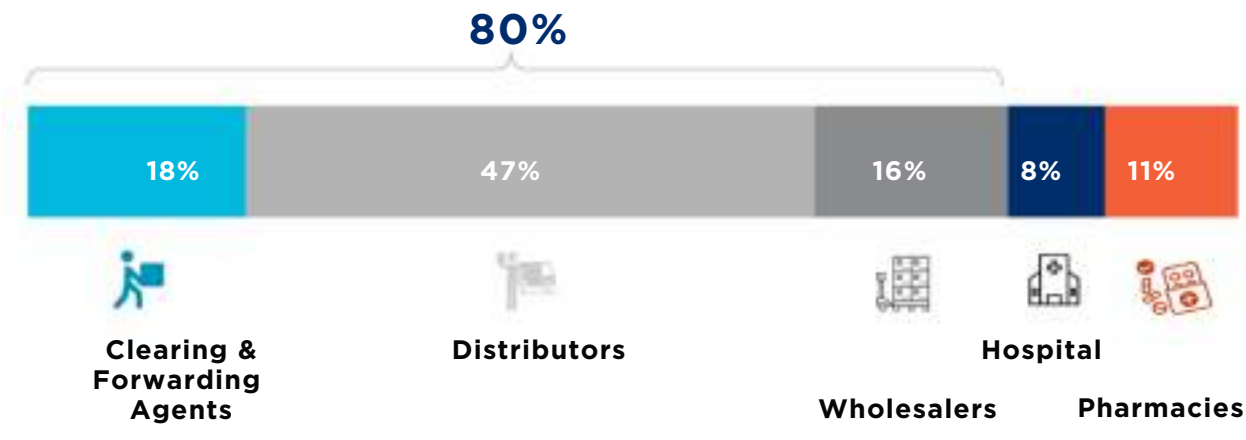
Third, the healthcare supply chain is also opaque, lacking transparency and end-to-end visibility. A lack of visibility and transparency of medicines and medical devices in the pharmaceutical supply chain is a persistent problem, especially in the domestic market and is one of the major causes of counterfeit products.

Our primary research interviews with key industry stakeholders confirm that over 80 per cent of pharmaceutical companies and medical device manufacturers do not have point-of-care visibility in the supply chain.

EXHIBIT 13

## More than 80% of companies do not have product visibility till the point-of-care

**Share of companies with different levels of healthcare supply chain visibility 100%= 121**




Source: Primary research interviews with industry stakeholders

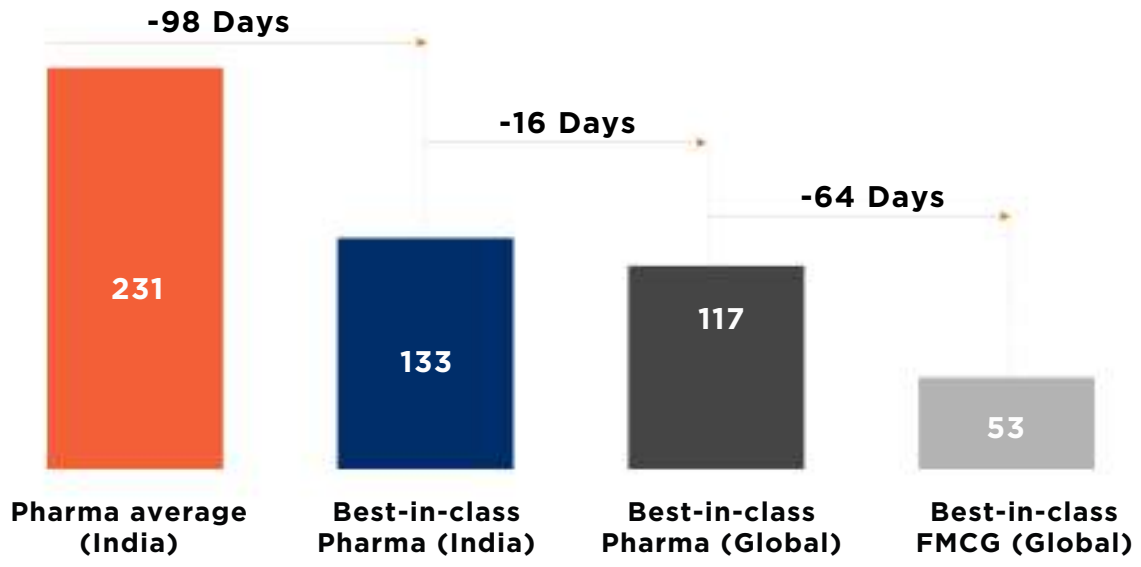
Fourth, due to the supply chain's fragmentation, manufacturing companies must operate multiple stocking units in different locations. The inefficiency in inventory management of pharmaceutical products adds high costs and slows down the distribution process. An average Indian pharmaceutical company maintains an additional inventory of 114 days compared to best-in-class global counterparts making an efficient inventory management system a burning issue.[36]

Fifth, the medical devices supply chain is slow due to enhanced scrutiny and quality checks at various levels. It leads to longer product lifecycles and more extended inventory holding periods. The absence of a data system to identify clear product non-conformity and an inefficient inventory management system further slows down the supply chain.

EXHIBIT 14

## Pharmaceutical inventory moves slowly in Indian companies compared to their global counterparts

**Inventory level, Number of days**




Source: Organisation of Pharmaceutical Producers of India

[36] India's Pharma Supply Chain: Does the Industry Have What It Takes to Win?, Organisation of Pharmaceutical Producers of India

Finally, the supply chain is inefficient because of sub-optimal transportation routes, a lack of network connectivity and higher average inventory levels that significantly add to operating cost of the supply chain. As a result, the total supply chain costs as a % of the cost of goods sold of the best-in-class pharma in India are eight percentage points higher than its global counterpart, emphasising the need for a cost-efficient supply chain.[37]

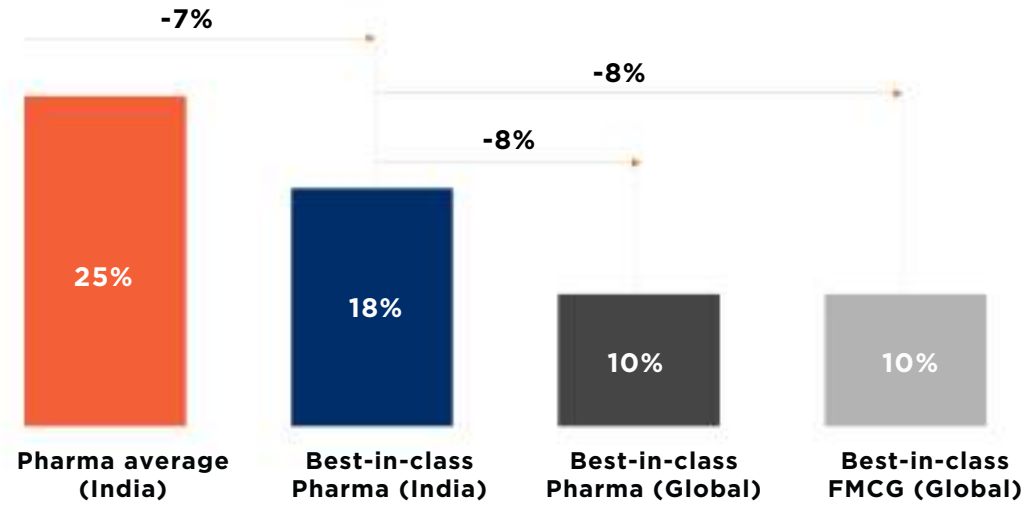
Inefficiency in the medical devices supply chain arises from high production and inventory costs. Additionally, the industry is also capital-intensive, with the current cost of financing ranging between 14-18%.[38]

Therefore, the cost of operating the supply chain increases significantly, pushing stakeholders at every level towards higher costs and squeezed margins.

EXHIBIT 15

## Supply chain costs are 15% higher in India compared to the best-in-class global pharma players

**Total supply chain cost, % of cost of goods sold**




Note: PP- Percentage Points, Supply chain costs include warehousing, inventory management and logistics costs
Source: Organisation of Pharmaceutical Producers of India

[37] India's Pharma Supply Chain: Does the Industry Have What It Takes to Win?, Organisation of Pharmaceutical Producers of India
[38] Medical Devices Making in India - A Leap for Indian Healthcare, Healthcare Federation of India

# Economic impact and cost of patient safety on healthcare supply chain

The current challenges of the pharmaceutical and medical devices supply chain are counterfeit medicines and devices, pilferage, wastage, medication errors and lack of timely availability putting patient safety at risk.

Drug Counterfeiting has become a problem of a significant magnitude globally. Substandard, Spurious, Falsely Labelled, Falsified and Counterfeit (SSFFC) medical products are often designed to appear genuine and unidentifiable from authentic medical products.

Their growth was previously a menace, but it has only escalated manifold with the outbreak of the COVID-19 pandemic.

"Counterfeit products are a great danger to society. For instance, the first lot of vaccines for COVID-19 were available in the market in Mexico before approval from any regulatory authority, posing a severe threat to supply chain security."

Global Healthcare Supply Chain Expert

The World Health Organisation (WHO) has observed that SSFFC medical products most commonly enter the legal supply chain at the distribution level through suppliers, distributors and wholesalers without due process. Therefore, an extended supply chain is more vulnerable to the ingression of counterfeit and spurious products.

Counterfeit products can enter the supply chain in two significant ways: Intrusion and Diversion. Under the Intrusion category, counterfeit products enter the supply chain in the form of wrong chemical compositions, duplicates or even expired drugs that are repackaged and forwarded. The expired medicines may not necessarily be harmful to the consumer, but they lose their potency, rendering them ineffective. Whereas under the Diversion category, products are either diverted to alternate channels of distribution or institutional supplies meant for a specific stakeholder is diverted towards other stakeholders. For instance, drugs and medicinal products intended to sell in India are diverted to other countries.

Finally, an inadequate legal framework, weak administrative measures, lack of brand and consumer awareness result in the growth of counterfeit products.

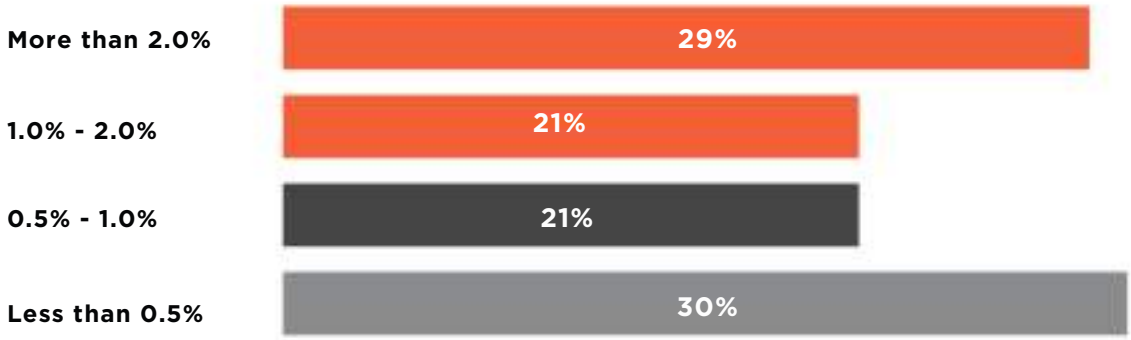
Pilfering from a stockpile of expired and rejected drugs may result in unfit products being diverted to the market for resale and misuse. Even at an international level, the appropriate guidelines for collecting and treating pharmaceutical waste products are missing. Only the World Health Organisation prescribes regulations for handling expired drugs during an epidemic where the government procures many medicines. The absence of a standard modus operandi for the disposal of expired and unused drugs poses an additional challenge to the healthcare sector.

There is also an economic loss due to improper management of expired products. For example, our research shows that half the drugs and device manufacturers incur more than 1% of their sales on expired and pilfered medicines.

EXHIBIT 16

# Half of the Indian drug and device manufacturers lose over 1% of their sales due to expiry and pilferage

**Waste as a % of sales for drugs and devices due to expiry and pilferage, 100% = 73**




Source: Primary research interviews with industry stakeholders

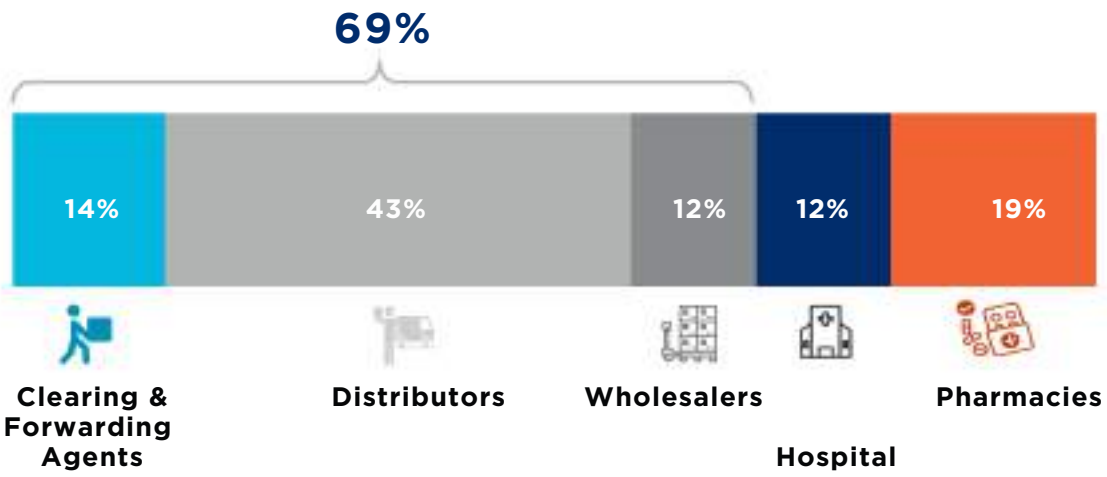
The reverse logistics of medicines and other medical products is a parallel aspect of the pharmaceutical supply chain and pharmaceutical waste products. Reverse Logistics is the backward or reverse movement of products from the end consumer to the manufacturer in the supply chain. One of the primary reasons for reverse logistics is the absence of efficient inventory management systems like FEFO (First Expiry First Out), which increases costs and vulnerability to counterfeit pharmaceutical products.

The hypothesis was confirmed in our primary research interviews where industry stakeholders lacked confidence regarding reverse logistics since 69% of the respondents mentioned that product recalls were a challenge to implement beyond wholesalers.

EXHIBIT 17

# 69% of respondents are not confident regarding the implementation of product recalls beyond distributors

**Share of different levels in pharma supply chain in terms of implementation**
**100%= 121**




Source: Primary research interviews with industry stakeholders

"An alarm system notifies products nearing expiry dates or waste products in advanced economies. So these products are recalled on that basis, but there is no such system in India."

Deputy General Manager, Pharmaceutical Company

Another result of the weak healthcare supply chain is the prevalence of Medication Errors (MEs). Medication Errors are preventable adverse reactions to a medication that jeopardises the patient's safety. These errors are multifaceted since they can occur at the stage of prescription, dispensation and administration.

Medication Errors harm a patient's health and can even result in severe patient injury or death, impairing the overall foundation of the healthcare system due to extended stays, wastage of drugs and medical products.

The causes of medication errors can vary from miscommunication amongst medical staff to improper storage, labelling, packaging, confusion of look-alike sound-alike (LASA) drugs, lack of information on current trends, protocols, medicine formularies or unawareness of the staff regarding new medicines, narcotics or high-alert medications.

Aside from human-made errors, system-generated errors also persist, which are often overlooked while identifying sources of the problem.

Finally, Inventory Management is a substantial challenge that can reduce the efficiency of the healthcare system. Without an adequate inventory, hospitals and pharmacies risk not providing timely treatment to the patients hence increasing their vulnerability to the ailment.

The primary focus areas of pharmacy inventory management systems are order management and cold chain storage management.

A proper order management system can predict stock demands, ensuring a consistent supply of essential drugs without frequent stockouts. Therefore, inventory control needs to determine stock quantity as an integrated approach to minimise storage and warehouse management costs without affecting the industry's functional efficiency. On the other hand, cold chain storage management is of immense significance because environmental factors, particularly temperature, can alter drug potency.

Additionally, the non-visibility of inventory is an added issue related to pharmacy inventory management systems.

# ROLE OF GLOBAL TRACEABILITY STANDARDS IN HEALTHCARE SUPPLY CHAIN RESILIENCE

Building Resilience in India's post-COVID
Healthcare Supply Chain

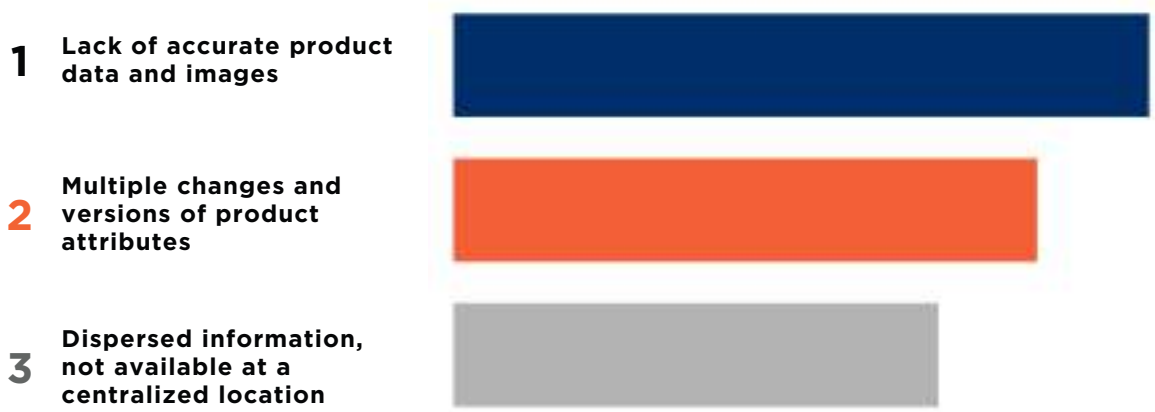
The benefits of advancing medical science have been compromised due to the gaps in the healthcare supply chain at both the global and country-level.

Our survey showed that more than 64% of respondents lack accurate data and images while maintaining data for drugs and devices. The other challenges were multiple changes and versions of product attributes and dispersed information not available at a centralised location.

EXHIBIT 18

## Manufacturers lack accurate product data with multiple versions of product attributes and dispersed information

**Top 3 challenges faced by respondents while maintaining product data, n = 121**




Source: Primary research interviews with industry stakeholders

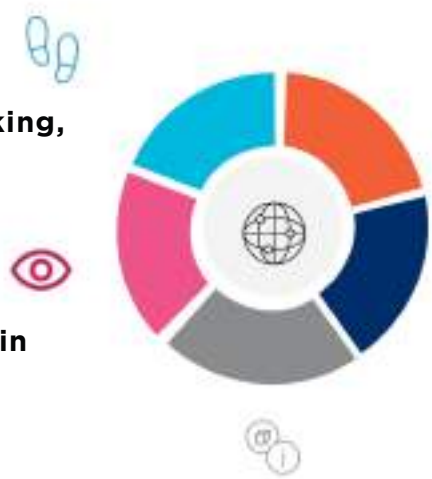
Global traceability standards help deal with supply chain challenges through a common language and a benchmark for all parties operating in the supply chain. This is especially true in the case of the healthcare industry, where the need for a synchronised system of standards with interoperability on a global level is a compelling necessity.

Global traceability standards ensure supply chain security, increased patient safety, and provide trust in the distribution of vaccines, medicines, and medical devices worldwide.

In addition, using global standards in healthcare delivery leads to five key benefits: product tracking, improved supply chain visibility, exchange of accurate product information, authentication and counterfeit detection and support in inventory management.

EXHIBIT 19

# Global standards offer five key benefits for healthcare supply chain management



**Help in product tracking, tracing and recall**

**Support inventory management**

**Improve supply chain visibility**

**Allow authentication and counterfeit detection**

**Enable exchange of reliable and accurate product information**

First, global traceability standards help in product tracking, tracing and recall, substantially improving the current traceability level in the healthcare supply chain by using unique identification keys at product, lot and unit level. It can also help manage First Expiry First Out (FEFO) and product recall.

Second, a harmonised barcode labelling system for different levels of pharmaceutical packaging creates visibility from product manufacturing to patient treatment.

Third, it enables the exchange of reliable and accurate product information. Manufacturers can access a shared repository for all product-related information using a cloud-based platform. Such platforms have transformed the retail landscape in India by enabling an exchange of reliable product information amongst manufacturers/suppliers, multiple retailers and e-commerce sites in an automated manner.

Fourth, global traceability standards can also lay the building blocks for authentication and counterfeit detection by securing the supply chain from intrusions and diversions with real-time data.

Finally, standards can aid in establishing an effective inventory management system by providing insights into the stock levels.

# Type of Product Identification Standards

The underpinning foundation of the standards is a unique identification key that contains all product-related information for every stakeholder in the supply chain. These Identification Keys enable universal and unique identification of supply chain elements from products (trade items) to assets and locations to logistic units.

The most widely used Identification Key is the Global Trade Item Number (GTIN), which uniquely and unambiguously identifies products. The GTIN can be encoded in a barcode or combined with an Electronic Product Code (EPC/RFID) to enhance traceability in the supply chain.

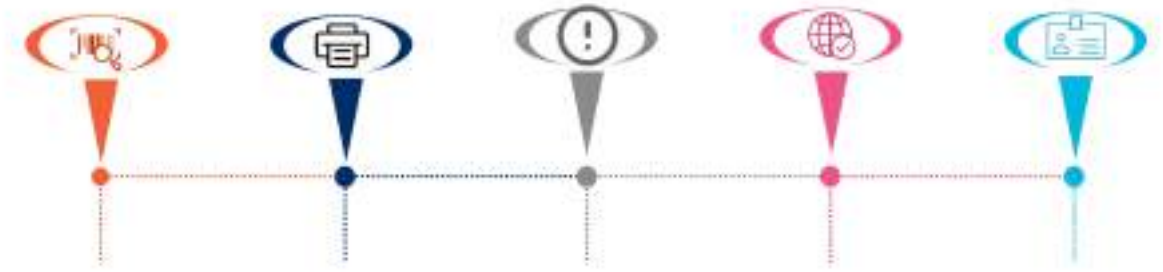
The packaging for pharmaceutical products and medical devices requires storing a large amount of information, including the product ID, batch/lot number, expiry date and serial number available on the packaging label. Also, there is a need to provide data at various levels of packaging and for a large number of products, e. g. medical devices such as surgical instruments and implants need to be directly labelled. As a result, the traditional linear barcode symbols (1D) might not always address the distinctive requirements of pharmaceutical and devices packaging, making two-dimensional (2D) barcodes necessary to capture all relevant product information.

DataMatrix, a two-dimensional (2D) barcode, is a tried and tested solution for barcode labelling. It was primarily introduced for healthcare applications. It may be printed as a square or rectangular symbol of individual dots or squares. This representation is an ordered grid of dark and light modules bordered by a finder pattern. The data is encoded using a series of dark or light modules based upon a pre-determined module size, grid size and mathematical formula. The DataMatrix is readable omnidirectionally (in a 360-degree orientation) and widely used globally in healthcare.

Quick Response (QR) Code is another commonly used 2D barcode available in the market. While regulatory bodies drive the implementation of DataMatrix for the fight against counterfeit of healthcare products and better control of the supply chain, QR codes primarily provide marketing information about a product through a link.

EXHIBIT 20

# DataMatrix offers five key benefits compared to traditional barcodes, making them the preferred choice for the healthcare industry



| Contains more information required for traceability eg. Item code, expiry date, batch number, and serial number. than traditional linear barcodes | Can be printed directly on the products. | Has a sophisticated error correction algorithm, compensating for lost or missing data due to extraneous marks or partial symbol damage. | World's most widely accepted standard in healthcare that provides unique identification and barcode marking for trade items. | The use of global Application Identifiers allows capturing multiple attributes in one barcode without any interpretation issue at the time of decoding. |
|---|---|---|---|---|

DataMatrix has a wide array of benefits over linear barcodes and QR codes:

- DataMatrix contains much more information than traditional linear barcodes required for traceability, like Item Code, Expiry Date, Batch number, Serial number, etc.
- It can also be printed directly on the products as per the feasibility.
- It has a sophisticated error correction algorithm, compensating for lost or missing data due to extraneous marks or partial symbol damage. With error correction, DataMatrix barcode symbols can recover from several types of physical damage.
- It is the world's most accepted standards system in healthcare and provides globally unique identification numbers and barcode marking for trade items.
- DataMatrix allows capturing multiple attributes in one barcode without any interpretation issue at the time of decoding.

Regulators across the globe have already directed the use of DataMatrix for successful drug traceability pilots on secondary packaging in Austria, Brazil, Colombia, Serbia, Switzerland and the United States, and primary packaging in Belgium. In addition, its use on pharmaceutical products is already specified by regulators in Argentina, France, India, Jordan, Korea, Saudi Arabia, Ukraine and the USA. It is also recommended for use on vaccines in Canada.

The Digital Link standard extends the power and flexibility of GS1 identification keys or barcode strings by making them part of the web. Through the digital link, brand owners and retailers can connect consumers, patients, and business partners to all types of information about their products – from images to expiry dates, medical product data, warranty registration and troubleshooting instructions.

The Digital Link feature is envisioned to enhance patient safety by enabling consumers to become more mindful of the products they consume. For instance, pharmaceutical manufacturers must provide product information to their patients in multiple languages, making leaflets cumbersome to produce. However, these leaflets could easily be substituted by an application that can read the pharmaceutical products encoded in the DataMatrix barcode on the package, redirecting the consumer to an electronic patient information leaflet.

Traceability solutions can also be enhanced significantly by utilising the same Digital Link barcode that would facilitate the identification of specific product batches (or even serialised products). This additional data in the barcode can lay the bedrock for provenance, recall and expiry of pharmaceutical products.

The widespread use of GS1 standards has revolutionised efficiency, accuracy, and cost-effectiveness in various industries. GS1 standards resemble the DNA of items and products moving through the value chain. By uniquely identifying the movement, it is possible to link items and products with relevant information. And hence, GS1 standards can play an essential role in the healthcare supply chain by identifying, capturing and sharing information in the following ways:

For identification:

- GS1 Identification Numbers are used to uniquely distinguish all products (trade items), logistics units, locations, assets, and relationships across the supply chain from manufacturer to patient.
- Global Location Numbers (GLNs) can identify any location that has meaning within a business scenario. The term location is used in a vast sense, besides physical locations also covering IT systems, departments and legal entities.
- Global Trade Item Number® (GTIN®) allows suppliers to create unique and standardized identifiers for products or cases.
- The Serial Shipping Container Code (SSCC) is the GS1 Identification Key used to identify a logistic unit. Some examples of logistics units are cases, pallets, or air cargo containers. The SSCC enables a logistics unit to be tracked individually to support order and delivery tracking and automated goods receiving.

For capturing information:

GS1 Data Carriers can hold varying amounts of data to accommodate different needs. The data encoded in GS1 Data Carriers enable easy reading of packaging and provide access to product information and visibility of product movement through the supply chain.

For sharing information:

With GS1 standards as the common language of business, trading partners can seamlessly share information to support data synchronization and exchange transactional and physical event data about products moving through the supply chain.

- The Global Data Synchronization Network (GDSN®) enables immediate electronic sharing of standardised, up-to-date product data, including GTINs, brand owner identifiers, weights, and dimensions. The GDSN can also be used to populate the US FDA Global UDI Database (FDA GUDID).
- Electronic Data Interchange (EDI) enables the computer-to-computer exchange of business documents among companies. Using standardised business messages, EDI empowers trading partners to communicate in a common language and conduct electronic commerce more accurately and efficiently.
- The Electronic Product Code Information Service (EPCIS) enables trading partners to capture and share information about the movement and status of goods in the physical world.

## Unique Device Identification (UDI)

A Unique Device Identification (UDI) system is intended to provide single, globally harmonised identification of medical devices through distribution and use, a globally unique device identifier. A single, global system of standards is fundamental to enable an efficient and effective implementation of UDI by all healthcare stakeholders worldwide.

## Medical Device Registry

A medical device registry is necessary to ensure that the device is safe, efficacious, and does not have negative consequences for the patient. The registry would function as a comprehensive database that includes all the mandatory information regarding the implanted medical device, which could further aid in quickly effecting product recall if required. Such real-life data from a registry would allow long term efficacy by allowing post-market surveillance. In addition, the registry would include patient-specific outcomes so that if a specific problem arose, it would be possible to track any related developments.

# INTERNATIONAL IMPLEMENTATION OF TRACEABILITY STANDARDS IN HEALTHCARE

Building Resilience in India's post-COVID
Healthcare Supply Chain

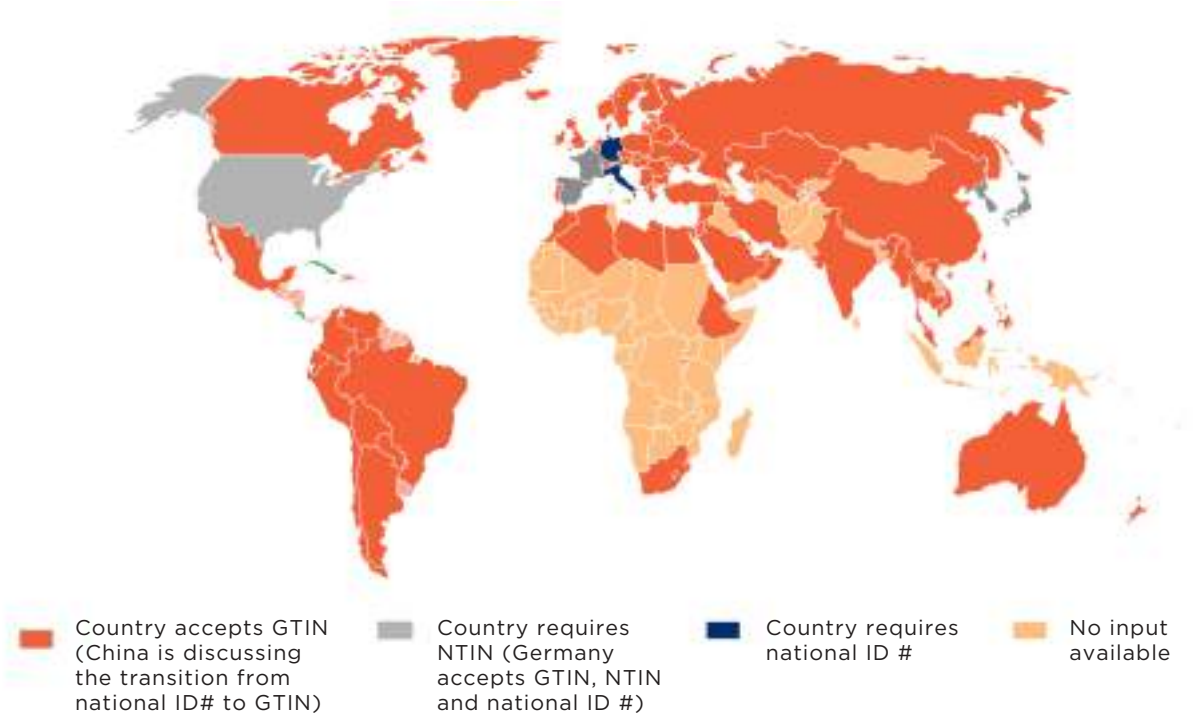
India issued draft regulations GSR 449 (E) dated 3rd June 2015 for track and trace systems; however, it faced several challenges in its implementation. At the same time, other countries have successfully adopted the global standards in traceability, bringing end-to-end visibility in their supply chain. These international experiences and learnings can help guide the implementation approach in India.

This chapter focuses on the features, challenges, and the current status of the track and trace systems operated in the United States and the European Union.

Argentina and Saudi Arabia are among the countries that have already put such a system in place, while China, the United States, and European Union (EU) member states are currently in the implementation phase.

EXHIBIT 21

## GTIN is globally accepted for product traceability in the healthcare industry




# Type of track-and-trace systems

In the pharmaceutical industry, two types of track and trace systems dominate the market: Point-of-dispensing check and Full track and trace systems. The Point-of-dispensing check system puts the onus on the retailers (e.g., hospitals, pharmacies, chemist shops, e-pharmacies) to validate the authenticity of pharmaceutical products at the time of dispensing to patients.

However, one disadvantage of such a system is that counterfeit products can be in circulation for months since the detection occurs at the point and time of dispensation. The Full track and trace system, also known as the Full Pedigree system, is a more comprehensive approach towards supply chain visibility.

From the point of manufacture to dispensation, every stakeholder in the legal supply chain is obligated to provide logistical information regarding the pharmaceutical products in circulation. Although this system adds complexities to the implementation process and the benefits outweigh the costs.

Track and Trace Systems can also be segmented into Centralised and Distributed Systems. Under Centralised Systems, each stakeholder handling the product publishes their traceability data to a central repository or database maintained by a regulatory body. This type of system has various benefits, e. g. it can be implemented in a phased manner.

In addition, the governance is managed by a single organisation such as the Ministry of Health and Family Welfare. Hence, the security of the system is not compromised. Moreover, it provides a high level of visibility across the supply chain because of a central repository.

However, it does suffer from drawbacks as there is a limited selection of solution providers in the market for such a track and trace system. And the system is complex to establish.

By comparison, in the Distributed System model, each stakeholder handling the product makes traceability identifiers available in a registry to enable the search capability of traceability data. This information can be stored anywhere since the registry provides the link and data-search mechanism. This requires collaboration amongst stakeholders. Additionally, data ownership and data exchange standards are clearly defined. However, this system offers limited visibility across the supply chain. It also requires effective coordination to ensure real-time information and takes a more extended timeframe for implementation.

# International experiences in track-and-trace implementation

In the United States of America, prescription drugs in finished dosage forms were not traceable throughout the pharmaceutical distribution supply chain. As a result, the US enacted the Drug Supply Chain Security Act (DSCSA) in 2013, which resembles a full track and trace system wherein all the stakeholders are responsible for providing relevant information. Furthermore, the act aims to achieve serialised item-level traceability by 2023; every supply chain partner can trace pharmaceutical products back to the initial manufacturer or re-packager. Currently, Lot-level traceability and verification along with Unique Serialisation have been accomplished. However, since unit-level tracing requires an advanced solution provider to accommodate varying capability levels of multiple stakeholders, a new system is under development to realise the potential of a whole track and trace system.

Likewise, Europe also faced threats from counterfeit medical products. It aimed to increase the security of manufacturing and delivery of medicines to enable patient safety. However, one of the main challenges faced by the EU was developing and managing a vast repository (database) connected to thousands of stakeholders and the need for an immediate response after verification of a product.

So the European Union Parliament established a point-of-dispensing check system in 2011 through its Falsified Medicines Directive (FMD). The directive came into full force in February 2019, and the point-of-dispensing check system is aided with risk-based checks by wholesalers and other intermediaries in the supply chain.

Each country has implemented a track and trace system most suitable for their own needs depending on its potential to overcome the challenges present.

Implementing a traceability system based on the unit of sale is an objective to be attained. It requires an extensive effort from stakeholders as new technologies must be adopted to enable substantial enhancement in patients' access to safe and efficacious products.

The case studies mentioned above have shed light on the gradual implementation process undertaken by the regulatory authorities. But more importantly, it must be noted how each of the three cases dealt with the problem differently, contingent upon their past experiences and the availability of resources.

# BUILDING RESILIENCE IN INDIA'S HEALTHCARE SUPPLY CHAIN

India's domestic healthcare supply chain faces numerous challenges, making it vulnerable and resulting in compromised patient safety and a significant economic burden. As COVID-19 highlighted the vulnerabilities, bringing them to the attention of the government, business and the public, it is time to take decisive actions to build resilience in the healthcare supply chain and protect it from unscrupulous actors and future disruption.

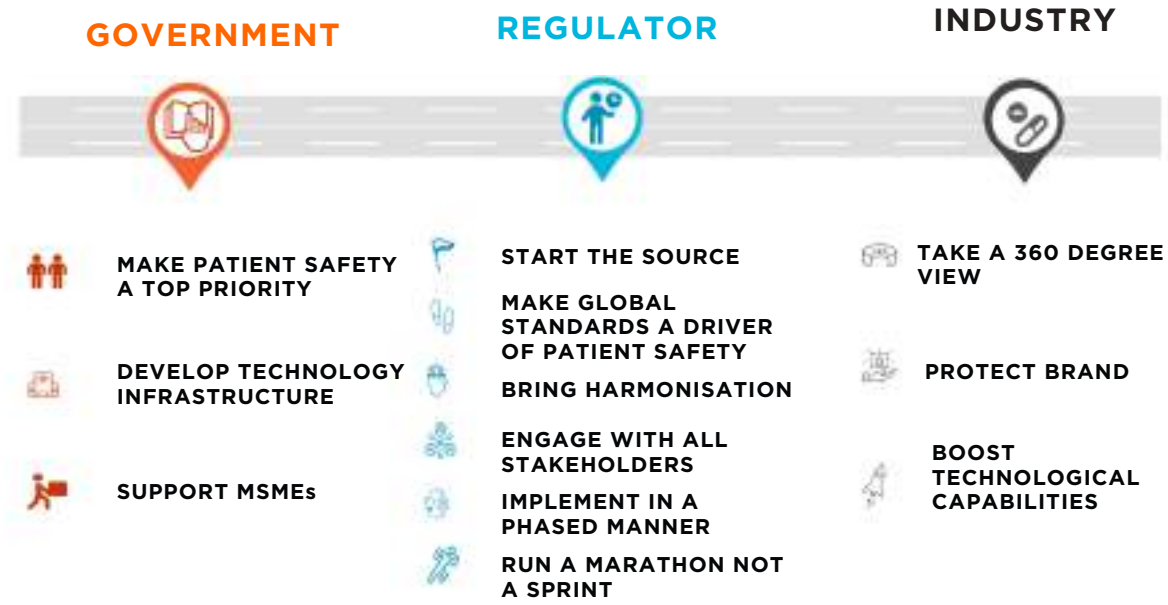
Making the supply chain resilient will require creating transparency and visibility through digitalisation and the use of global standards which facilitate interoperability and sharing of information.

While India has its track and trace system for the export market, it can also learn from the experiences of other countries globally.

This chapter lays down key imperatives for three stakeholders: Government, Regulators, and Industry to build a future-proof supply chain that can be transparent, make data visible, and allow track and trace.

EXHIBIT 22

## The government, regulator and industry need to work together to realise a resilient healthcare supply chain




# Government

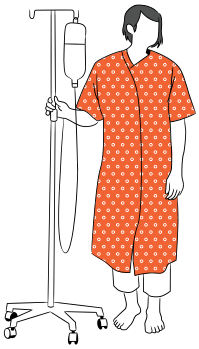
The government plays a central role in leading the way forward because of the many resources at its disposal and its ability to implement programmes through its patient-centric initiatives and policies to improve patient safety. The Government of India has been extensively focusing on better healthcare for all through its National Health Policy 2017. The NHP is patient-centric and a quality-driven policy that addresses health security and Make-in-India for drugs and devices.

The policy proposes raising public health expenditure to 2.5% of the GDP in a time-bound manner.[39]

Moreover, it advocates extensive deployment of digital tools for improving the efficiency and outcome of the healthcare system. The government can further help make the healthcare supply chain resilient by bringing patient safety to a top priority, developing technology infrastructure and supporting MSMEs.

[39] National Health Policy 2017

## Make patient-safety a top priority



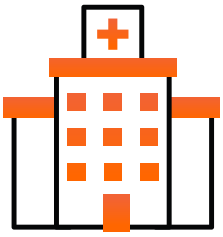
Patient safety is the cornerstone of all mature healthcare systems. Unfortunately, the scope of errors increases as the complexity in a healthcare setting increases. At the same time, the government and industry stakeholders across the supply chain bear economic costs.

Medication errors are avoidable harm in healthcare systems, making them extremely important to reduce adverse reactions that endanger human lives and increase healthcare expenditure.

To ensure successful implementation of patient safety strategies: the government can formulate clear policies directing stakeholders towards revamping their processes, gathering data, utilising technologies and digital platforms to share information, and sensitising staff in handling adverse events.

## Develop technology infrastructure

A robust supply chain with end-to-end visibility will require a technological backbone to capture and share real-time data related to supply-chain events accurately and cost-effectively; transformation in the digital infrastructure is a prerequisite that precedes all other measures.



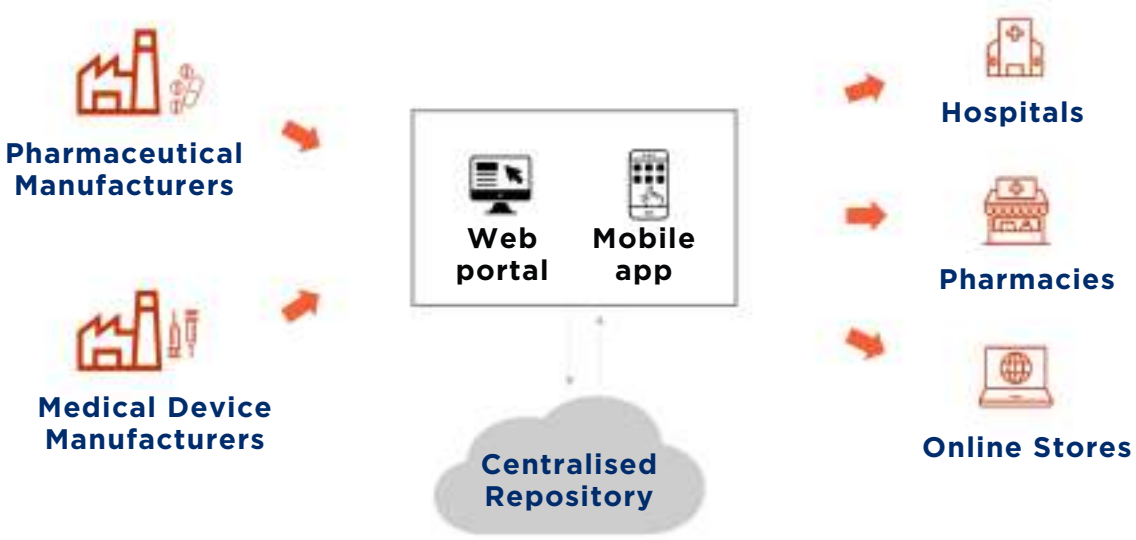
The proposed digital infrastructure will first have essential universal and unique identification of drugs or devices. Second, the product (drugs and devices) data will need to be captured in a centralised repository to provide real-time information on the movement of pharmaceutical products and devices. Third, tracking of drugs or devices is enabled by capturing relevant data related to the physical movement of drugs and devices. Finally, a shared web portal and a mobile application will provide a user-friendly interface to patients and regulators to validate or trace the origin of the drug or device, making it a stepping stone towards establishing a standard traceability system.

"The government should provide a web portal, then only it is possible to implement a whole track and trace system. In addition, this web portal will help in insights generation, sales increase, and inventory management."

Assistant General Manager,
Pharmaceutical Company

EXHIBIT 23

## The proposed digital infrastructure will have a centralised data repository to enable track and trace for drugs and medical devices




Building a robust technological infrastructure will make the healthcare supply chain resilient through tracking products at every step from the manufacturer to the point-of-dispensing and enabling reporting in case of a recall or other supply chain incident. In addition, it will equip the stakeholders to generate insights, leading to a reduction in supply chain disruptions.

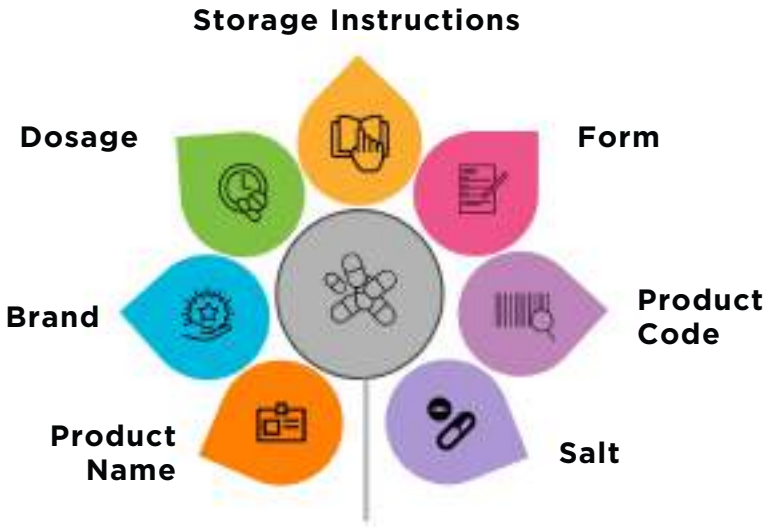
India could also learn from experiences of their global counterparts of implementing track and trace systems. For example, pharmaceutical companies in the US and Europe must provide product data to National Drug Repositories that identify drugs and medical devices.

Similarly, a common and comprehensive database for all pharmaceutical medicines and medical devices could bring consistency in the domestic identification of products.

Furthermore, our research interviews have shown that a majority of the pharmaceutical companies and medical device manufacturers already capture a uniform set of product information which could be a starting point to further build upon.

EXHIBIT 24

## Pharmaceutical companies use seven key attributes for product data management




Source: Primary research interviews with industry stakeholders

"A quick scan of the 2D barcode helps in inventory management. But there is no cloud-based system currently available, so there is no use in printing such data. The main issue is that no stakeholder sees merit in scanning the data until a robust cloud-based system is available. "

Manager Project & Engineering,
Pharma Retail Company

## Support MSMEs

India is home to 3,000 pharmaceutical companies[40] and around 750-800 medical device manufacturers.[41] And while there is a handful of large-scale players in the industry, it predominantly consists of micro, small and medium enterprises (MSMEs). Moreover, there are only 3,000 hospitals with a bed size of 100 and above, mainly located in metropolitan cities.[42] On the other hand, around 40,000 hospitals that cater to India's rural population have a bed size of below 30.[43]

Small scale manufacturing companies and hospitals do not have the financial capacity to transform their manual systems independently. In addition, improving supply chain visibility using barcodes, printers, and other technologies in production and distribution entails investment beyond their means. Thus, financial assistance from the government is necessary for the industry to implement automated systems.

[40] Indian Pharmaceutical Industry, India Brand Equity Foundation
[41] Medical devices, Invest India
[42] Primary research with industry stakeholders
[43] ibid.

"Smaller manufacturing companies cannot afford an automated system for traceability; hence, they require government support."

Vice-President,
Pharmaceutical Company

The government needs to provide subsidies and concessions to small-sized manufacturers to incorporate track and trace systems that require machinery for re-equipping manufacturing and packing lines. It can also offer free training courses to the workforce to reorient their skills towards such technologically advanced techniques.

The government also needs to incentivise healthcare industry associations to provide short-term courses to develop allied healthcare personnel since they support the core activities. For example, a study on inventory management systems will help improve business efficiency and prevent errors in treatment administration, ultimately ensuring patient safety.

# Regulators

Regulators' continuous and concerted efforts are indispensable for achieving the government's plans. While the government can sanction policies and release notifications to lay the foundations of a track and trace system, the regulatory bodies can ensure the implementation of government directives based on their area of expertise and impart learnings from past experience into the rollout of an end-to-end visibility system.

Regulators can take several actions to implement a track and trace system successfully:

## Start at the source

Identifying and capturing essential product attributes with the help of unique identification encoded in a barcode and labeled at the source, i.e. at the time of manufacturing and packing medicines or devices in the factory, enables healthcare supply chain traceability. However, doing so at any point in the downstream supply chain will be error-prone and labour intensive, making the process unsustainable in the long run.

"The onus of barcoding lies primarily on the pharmaceutical and medical device manufacturers."

Director-General,
Healthcare Providers Association

A universal and unique identification through barcoding at the source will bring accuracy in product data capture, commonly termed as master data, which can then be shared through a shared repository and used by all the stakeholders in the supply chain. As any stakeholder scans the barcode, the information will be captured in the shared repository, making the info seamless and accessible for everyone else in the supply chain, making the system interoperable.

In addition, the barcode labelling will enable and support counterfeit detection, inventory management, right dispensing and recall process management across the healthcare supply chain.

## Make Global Standards a driver of patient safety

Many Indian pharmaceutical companies and device manufacturers already fulfil international export regulations; however, the domestic market lacks adherence to such standards.

Our research shows that companies clearly understand the benefits accruing from Global Standards. However, there seems to be inertia to move forward because of an absence of regulatory measures to ensure supply chain traceability. For example, the National Accreditation Board for Hospitals & Healthcare Providers (NABH) has mentioned that hospitals must ensure traceability of services, drugs and medical products. Still, it does not specify the method resulting in non-uniform implementation by the healthcare providers. Including such standards as directives in guidance documents can nudge hospitals and healthcare providers in the right direction.

"Pharmaceutical exports from India have to fulfil global regulatory requirements. Therefore manufacturers have implemented traceability solutions, whereas a lack of mandate for the domestic market has held back its implementation in India"

Deputy General Manager,
Pharmaceutical Company

As drugs and medical device manufacturers need to incur upfront costs to implement traceability systems into their current operations, regulatory requirements can motivate them to incur the costs without losing their competitive edge to other players in the industry.

Furthermore, comprehensive international case studies provide evidence of the importance of regulations for bringing desired changes in the healthcare supply chain practices.

## Bring harmonisation

Uniformity in the barcoding labelling standards across the packaging levels is essential for achieving a resilient supply chain. A harmonised barcode label on each level of drug and device package enables all stakeholders in the supply chain to capture events such as dispatching, receiving and storing, bringing visibility in the supply chain and making of tracking products effectively.

"There must be a harmonised approach for identifying drugs so that everyone across countries can use the same identification scheme for traceability. "

Global Healthcare Supply Chain Expert

Moreover, a harmonised approach towards barcode labelling for exports and the domestic market by various procurement agencies in the government and private sector can ensure standardisation, interoperability and cost-effectiveness.

## Engage with all stakeholders

Industry stakeholders need to be engaged right from the beginning to seek their inputs, understand on-ground challenges and collaborate to develop an implementation roadmap.

Regulators also need to communicate upcoming changes to all stakeholders, giving them sufficient lead time to prepare for the implementation. Moreover, communication of deadlines needs to reinforce the government's seriousness in establishing a standard traceability system.

When the stakeholders are promptly made aware of the required changes and deadlines, they can re-align their current practices to the impending changes.

"Involve all stakeholders from the beginning and communicate the changes to them. For example, South Korea did a fantastic job involving the stakeholders at every step from the start."

Global Healthcare Supply Chain Expert

A four-way dialogue between the concerned stakeholders- technology and subject-matter experts, industry associations, the pharmaceutical industry and the government is essential to reach a consensus on the new system. These stakeholders need to be involved in the policy formulation stage to prevent future roadblocks.

Furthermore, feedback from the stakeholders at regular intervals will strengthen the system. It is also essential to promote awareness about the benefits of a traceability system via television, social media and other communication channels.

## Implement in a phased manner

While an 'all-at-once' approach may give an impression of a shorter timeline to implement in theory, it commonly leads to issues in the long run when faced with on-ground challenges. Therefore, to ensure successful implementation of a robust traceability system, pharmaceutical drugs and medical devices can be prioritised, gradually extending traceability measures.

EXHIBIT 25

### A phase wise implementation will ensure effective prioritisation and frictionless implementation

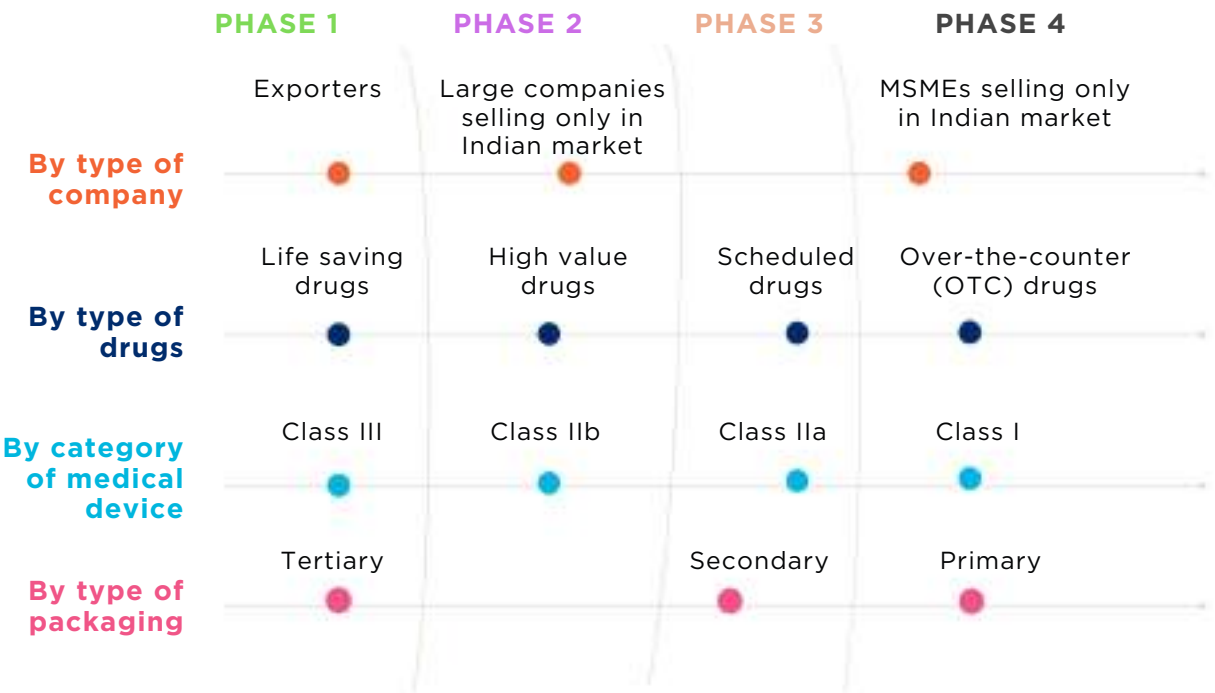
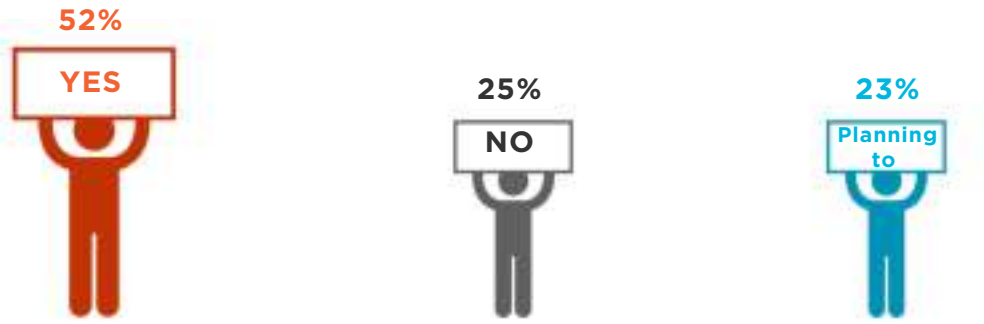


EXHIBIT 26

# Over 50% of respondents are already using barcodes for some products, making it easier for them to extend to all products

**Percentage of respondents partially using barcodes for use in Indian market 100%= 121**




Source: Primary research interviews with industry stakeholders

Firstly, those drug manufacturers who are already familiar with the exports portal or barcodes could extend the system to the domestic market. Our primary research surveys show that more than 50% of the respondents utilise barcodes in some cases or for some products.

Hence, it could be easier for them to extend their application for other products in the domestic market.

"For exports, barcode labelling for Medical Devices is staggered, where priority is given based on the risk associated with the product. So, in the European and the USA market, importance is given to the Class 3 category of products followed by Class 2A, Class 2B, and then Class 1."

Senior Engineer,
Medical Device Manufacturer

Secondly, the products could be selected and prioritised based on their criticality to save a human life. Life-saving drugs should be given the top priority, followed by high-value drugs, scheduled drugs, and then over-the-counter (OTC) products.

Barcode labelling for medical devices can be done in a staggered manner where priority is given based on the risk associated with the product.

For instance, in the European and the American markets, medical devices are classified into four categories: Class III category of products with the highest degree of risk followed by Class IIb, Class IIa and then Class I products with the least amount of risk.

Thirdly, there is a need to prioritise by packing levels. Herein, barcoding and serialisation can commence with tertiary and secondary levels of packing and then gradually transition to primary level packing that would enable item-level traceability in the long run.

## Run a marathon not a sprint

Regulators and the Government have to give reasonable timelines for implementing track and trace systems. Implementing such a system presents challenges because of the diversity of manufacturers, vast geographic scope, a need to run multiple systems in the interim and the learning curve required to become conversant and comfortable with the new system.

International experience shows that different countries have set implementation timelines to match their unique circumstances.

## Support product pricing

The National Pharmaceutical Pricing Authority (NPPA) is a government regulatory agency that controls the prices of pharmaceutical drugs in India. The NPPA can marginally increase the price of pharmaceutical drugs and medical devices to aid the manufacturers in covering the additional costs required for installing traceability systems.

# Industry

Pharmaceutical companies, manufacturers, distributors, hospitals, and pharmacies make up the pharmaceutical supply chain. However, more often, these individual stakeholders are focused on the activities relating to their area of specialisation. Thus, macro-level plans can fail to achieve the desired results when stakeholders view the different elements in isolation, making it crucial to gain the cooperation of all stakeholders in generating far-reaching benefits.

## Take a 360 degree view of costs and benefits


Implementing a track and trace pedigree system would require additional costs by each stakeholder to re-align their predominantly manual systems to a digital one. Our primary research confirms the focus on cost for a majority of stakeholders. However, there is a need to shift focus from the costs incurred to the benefits that will accrue from substantially enhanced future processes. To put it simply, the benefits to incorporate end-to-end visibility into the pharmaceutical supply chain outweigh the costs.

"Investment is one of the barriers for manufacturers, but on the other hand, many manufacturers also agree that there are substantial benefits that they derive from it."

Global Healthcare Supply Chain Expert

The information generated from data repositories would enable inventory visibility at various stock points, improving demand forecasting and inventory planning for manufacturers, hospitals and pharmacies alike.

In addition, utilising essential inventory management tools like the FEFO (First Expiry First Out) method, ABC inventory analysis, and the 5S lean manufacturing methodology can improve stock visibility, ensuring timely availability of essential medical products.

"There is a favourable change towards data management with the growth of e- pharmacies, which require a shift of focus towards RFID, barcode and serialisation to manage inventory because of a need to manage a large volume of products."

Deputy General Manager,
Pharmaceutical Company

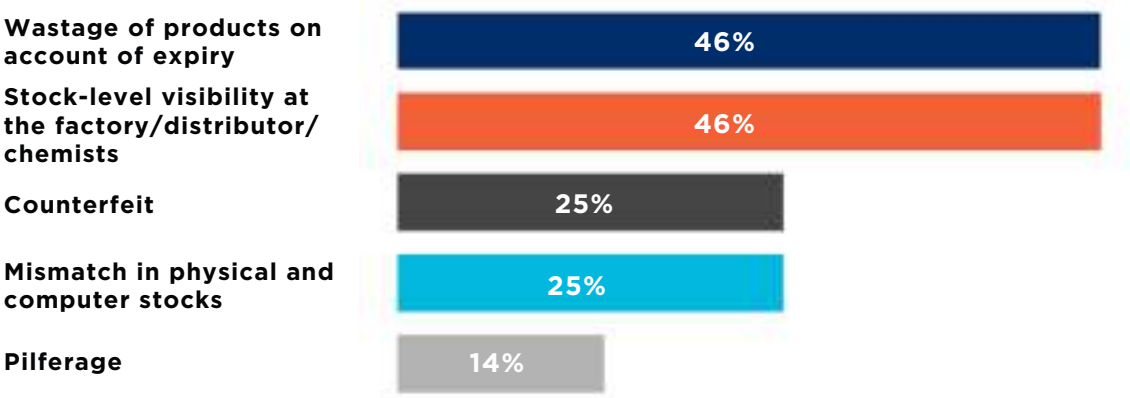
Our survey with drugs and medical device manufacturers found that 46% of respondents face challenges related to product wastage due to expiry.

They also lack stock-level visibility with other stakeholders in the supply chain due to poor inventory management systems.

EXHIBIT 27

# A lack of accurate product data and sharing leads to waste, counterfeit, high inventory, and pilferage across the healthcare supply chain

**Share of different challenges faced as a pharmaceutical/medical device manufacturer 100% = 121**




Source: Primary research interviews with industry stakeholders

There could be a significant reduction in the scope for recall of medicines and medical devices due to better management of products from increased supply chain visibility. Bedside scanning could also reduce preventable medication errors and adverse drug events (ADEs) in hospitals. Furthermore, hospitals and pharmacies can replace current manual systems to ensure optimum inventory levels, match product data with master catalogue and validate accounts receivables and payables with automated systems.

With the reduction in time spent on manual activities, healthcare providers can shift their focus from non-core activities to patient care, enhancing patient safety considerably. Finally, the traceability systems will help detect counterfeit medicines and medical devices in the supply chain, enabling regulators, manufacturers and patients to take appropriate actions and cut down loss of sales of genuine products.

## Protect brand


In today's day and age, counterfeiting has become a global industry, threatening public safety, eroding consumer confidence, and destroying brand reputation. Counterfeit products are available in the market with little to no variation in their packaging, making it difficult to distinguish them from genuine medical products. Falsified products, especially those belonging to healthcare, can have serious adverse effects on the well-being of a person. Moreover, there is also a business hazard of counterfeit drugs, which contributes to a loss of revenue for manufacturers and the government.

An effective traceability system will help pharmaceutical companies and medical device manufacturers protect their brands against counterfeit products and unauthorised distribution by making every product unique, secure, and traceable.

"Uniform barcoding standards will significantly decrease medication errors, ensuring patient safety."

MD & MCP,
Pharma Retail Company

It will also allow consumers to verify the authenticity of products in real-time.

Finally, brand protection will increase companies' revenue and the safety of consumers with end-to-end supply chain visibility.

## Be tech-savvy

The healthcare industry can practically accomplish end-to-end visibility in the supply chain by replacing and supplementing current technological infrastructure with advanced and modern technology. For example, the printing of barcodes on medicines and medical devices on different packing levels require advanced printer settings. Further, the traceability system needs to be backed up by cloud-based servers to store product and event-related information for master data management.

"Counterfeiting, pilferage and wastage of products are prevalent in India due to lack of safeguards. Identifying these products will become easier with RFID and Barcodes on primary, secondary and tertiary levels of packaging."

Deputy General Manager,
Pharmaceutical Company

More importantly, the use of two-dimensional (2D) barcodes can be leveraged by using DataMatrix on primary and secondary levels of packing due to its accuracy and numerous advantages over one-dimensional (1D) barcodes and QR codes. Finally, parent-child relationship mapping on the different levels of packing can further enhance traceability by providing real-time locations of the products.

After a comprehensive evaluation of the current supply chain practices, it can be concluded that India still has a long way to go. The country has enormous potential to tap into its existing resources, but more importantly, a strong-willed initiative from the stakeholders is required to improve the present situation. The government, regulator and the industry are the three most important stakeholder groups that have to cooperate in revolutionising the current supply chain practices. Their efforts will motivate the individual players in the industry towards building a resilient healthcare supply chain.

# Conclusion

This report has meticulously discussed the acute challenges facing the Indian healthcare sector. It has emphasised the current attributes of the pharmaceutical and medical devices supply chain that make it inadequate for end-to-end visibility. The industry stakeholders confirmed these challenges in the primary research surveys and interviews. Additionally, other sets of challenges focused on the economic costs borne by the patients and how these challenges further endanger patient lives putting safety at risk.

Further chapters in the report highlight the various examples of track and trace systems globally. Through the use of global standards, countries like the United States of America and the European Union could instill visibility into their supply chains.

Finally, the report concludes with a set of recommendations for the different stakeholders in the healthcare industry. It lays down the way forward and approaches for building a resilient supply chain in the backdrop of the COVID-19 pandemic. The government, regulatory bodies and the industry players are the three key stakeholder groups that will have to collaborate to realise the full potential of a traceability system.

# Abbreviations

| | |
|---|---|
| **ABDM** | Ayushman Bharat Digital Mission |
| **ADRs** | Adverse Drug Reactions |
| **CAGR** | Compound Annual Growth Rate |
| **CPSE** | Central Public Sector Enterprises |
| **C&F** | Clearing and Forwarding Agents |
| **CoWIN** | Covid Vaccine Intelligence Network |
| **CPOE** | Computerised Physician Order Entry |
| **DSCSA** | Drug Supply Chain Security Act |
| **EDI** | Electronic Data Interchange |
| **EPC** | Electronic Product Code |
| **EPCIS** | Electronic Product Code Information Service |
| **EU** | European Union |
| **FDA GUDID** | US FDA Global Unique Device Identification Database |
| **FEFO** | First-Expiry-First-out |
| **FMD** | Falsified Medicines Directive |
| **FY** | Financial Year |
| **GDP** | Gross Domestic Product |
| **GDSN** | Global Data Synchronization Network |
| **GeM** | Government e-Marketplace |
| **GLNs** | Global Location Numbers |
| **GoI** | Government of India |
| **GTIN** | Global Trade Item Number |
| **HWCs** | Health and Wellness Centres |
| **ITS** | Ilaç Takip Sistemi |
| **LASA** | Look-Alike Sound-Alike |
| **MEs** | Medication Errors |
| **MSMEs** | Micro, Small and Medium Enterprises |
| **NABH** | National Accreditation Board for Hospitals & Healthcare Providers |

| | |
|---|---|
| **NHA** | National Health Authority |
| **NHP** | National Health Policy |
| **NPC** | National Product Catalogue |
| **NPPA** | National Pharmaceutical Pricing Authority |
| **NSQ** | Not of Standard Quality |
| **OTC** | Over-the-counter |
| **PMBI** | Pharmaceuticals and Medical Devices Bureau of India |
| **PMBJP** | Pradhan Mantri Bhartiya Janaushadhi Pariyojana |
| **PM-JAY** | Pradhan Mantri Jan Arogya Yojana |
| **PP** | Percentage Point |
| **PPP** | Public-Private Partnership |
| **QR** | Quick Response |
| **R&D** | Research and Development |
| **RFID** | Radio Frequency Identification |
| **SSCC** | Serial Shipping Container Code |
| **SDGs** | Sustainable Development Goals |
| **SKUs** | Stock Keeping Units |
| **SSFFC** | Substandard, Spurious, Falsely Labelled, Falsified and Counterfeit |
| **TPCI** | Trade Promotion Council of India |
| **UDI** | Unique Device Identification |
| **UHI** | Unified Healthcare Interface |
| **USTR** | United States Trade Representative |
| **WHO** | World Health Organisation |
| **WMTPC** | Wellness and Medical Tourism Promotion Committee |
| **1D** | One-dimensional |
| **2D** | Two-dimensional |

# Acknowledgements

This report results from the collective contribution of healthcare industry stakeholders in India and the GS1 Global Office. We would take this opportunity to thank the pharmaceutical and medical device manufacturers for their invaluable insights on the current challenges facing the healthcare supply chain in India. We also take this opportunity to thank the hospitals and retail pharmacies for their willingness to share on ground realities to make this study comprehensive and well rounded.

We would like to extend our gratitude to the stakeholders who responded to our surveys. And although it would be difficult to mention all by name, the report would have been incomplete without the insights that we generated from the surveys as a result of their participation.

At this stage, we must express our appreciation for Ms Ulrike Kreysa and Ms Geraldine Lissalde-Bonnet from the GS1 Global Office. They have been kind enough to share their expertise in the healthcare domain. We gained a global perspective through their insights, which would be a great help in making India's healthcare supply chain resilient.

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