Blockchain-Based Solution for Tackling Counterfeit Drugs in India

By

Pavlin Kaur Johar

Dissertation submitted in partial fulfillment of the requirements of the degree

MBA Hospital and Health Management

Academic year, 2018-2020

The IIHMR University, Jaipur

1, Prabhu Dayal Marg, Sanganer, Airport
Jaipur 302029, Rajasthan
Ph: 0141 3924700, Fax: 3924738
Website: **www.iihmr.edu.in**

Blockchain-Based Solution for Tackling Counterfeit Drugs in India

By

Pavlin Kaur Johar

Dissertation submitted in partial fulfillment of award of

MBA Hospital and Health Management

Academic year, 2018-2020

IQVIA Consulting and Information Service India, Pvt. Ltd., Delhi

The IIHMR University, Jaipur

1, Prabhu Dayal Marg, Sanganer, Airport
Jaipur 302029, Rajasthan
Ph: 0141 3924700, Fax: 3924738
Website: **www.iihmr.edu.in**

IMS Health & Quintiles are now IQVIA

June 19, 2020

TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Pavlin Kaur Johar** was associated with **IQVIA Consulting and Information Service India Pvt. Ltd.** as an **Intern** and the internship period was from 3rd February 2020 till 12th June 2020.

This certificate is issued in recognition of successful completion of 4 months & 10 days of **her Project** in the department of **Public Health.**

We wish her all the best for future endeavors.

For IQVIA Consulting and Information Service India Pvt. Ltd.

S. Yamini Krishnan

Sr. Director HR, AMESA

IQVIA Consulting And Information Services India Private Limited
Unit No. 902, 9th floor, B-Wing, Supreme Business Park,
Supreme City, Hiranandani Gardens, Powai,
Mumbai, 400076, India.
CIN : U74140MH2003PTC142482

Tel: +91 22 7109 7200
Fax: +91 22 7109 7222
iqvia.com

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled **Blockchain-Based Solution for tackling counterfeit drugs in India** and submitted by **Dr. Pavlin Kaur Johar** , Enrollment No **0795** under the supervision of **Dr. J.P. Singh** for award of **MBA in Hospital and Health Management** in Health and Hospitals of the University carried out during the period from 3rd February 2020 to 3rd May 2020 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institute or other similar institution of higher learning.

Signature

ABSTRACT

1. **TITLE: -**

Blockchain-Based Solution for Tackling Counterfeit Drugs in India- A Review

2. **INTRODUCTION: -**

The issue of counterfeit drugs is a global concern, with every country currently tackling its menace. It is an increasing worldwide dilemma with a profound impact on lower income countries (LIC) and lower middle-income countries.

Although there is no clear international definition of counterfeit medicines, the most widely accepted definition is the one given by the World Health Organization in 1992 defining counterfeit medicine as the one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging. As per the recent WHO estimates, an estimated 1 in 10 medicinal products circulating in low- and middle-income countries is either substandard or falsified[1]

Due to easier drug access through various channels today, the potential risks of exposure to counterfeit products has manifolded dramatically. In addition, counterfeit medicines have become more difficult to detect as counterfeiters have become more innovative in manufacturing and distribution of fake drugs. Such practices are a major public health concern, cause significant financial loss and damage the reputation of pharmaceutical companies, dispending pharmacies and health care practitioners. The overall result can be a complete loss of public trust in the healthcare system.

A major challenge facing pharmaceutical industries today is the traceability and security of its supply chain, from raw materials to manufacturing and on to the consumer. Although the industry has developed several tracking solutions in the past, such as barcodes or radio-frequency identification (RFID) tags, the problem of counterfeiting continues due to lack of real-time data and inefficient data integration across different suppliers. In India, fake medicines are a major concern with approximately 3% of drugs being substandard or counterfeit, as per National Drug survey 2014-2016, conducted by National Institute of Biologics, Ministry of Health & Family Welfare[2.]

Owing to these factors, the introduction of 'Blockchain-based solutions' to the pharmaceutical industry – A decentralized and distributed ledger which will log in data with respect to the individual transactions into a common blockchain, overseen by a Government regulator. This level of monitoring and tracking implies real-time visibility of any tampering or falsifying activities, which can be recorded and rectified immediately

3. Objectives

- To understand the current scenario of the pharmaceutical market, at a global and National level.
- To understand counterfeit drugs and their implications in the drug supply chain.
- To understand the perspectives of each of the stakeholders – Manufactures, Retailers and Pharmacists – around block chain technology.
- To analyze block-chain based solution and their growing implication in the pharmaceutical industry.
- Recommendations to develop the way forward.

4. Methodology

Literature search across published studies, thought leadership papers, journals, analyst commentary and blogs and news articles were conducted to collate and assimilate the material currently available online to provide a comprehensive understanding.

5. Implication

This research is an attempt to understand how blockchain-based solution can be used to tackle the growing menace of sub-standard drugs in India and improve the availability, affordability and access to premium quality medicines.
In addition, it also provides thought provoking insights and recommendations to help in execution of nation-wide implementation soon.

ACKNOWLEDGEMENTS

I feel privileged in expressing my kindest gratitude to **Mr. Anurag Saxena (Principal Public Health- IQVIA Consulting and Information Services Pvt. Ltd.),** under whose guidance and supervision this study was conducted. The keen interest he evinced throughout this period and the graciousness with which he gave his valuable advice was his exclusive acumen.

Bearing in mind the previous, I would like to take this opportunity to express my deepest gratitude and special thanks to my mentor, **Dr. J.P. Singh, IIHMR University, Jaipur**, for guiding and keeping me on the correct path throughout the period of internship.

I express my deepest thanks to **Shyanne Dewan (External Consultant at IQVIA Consulting and Information Services Pvt. Ltd, Delhi)** for taking part in useful decision and giving necessary advises and guidance. I choose this moment to acknowledge her contribution gratefully.

In the end I thank all those fellows and colleagues who have helped me throughout this study and my apologies to anyone whose name I would have inadvertently forgotten to mention here.

Table of Contents

List of Figures

TITLE: Blockchain-based solution for tackling counterfeit drugs in India

INTRODUCTION

The issue of fake medications is a worldwide worry, with each nation as of now handling its danger. It is an expanding overall issue with a significant effect on lower salary nations and lower center pay nations.

Although there is no away from meaning of fake prescriptions, the most generally acknowledged definition is the one given by the World Health Association in 1992 characterizing fake medication as the one which is intentionally and deceitfully mislabeled as for personality as well as source. Fake items may incorporate items with the right fixings or with an inappropriate fixings, without dynamic fixings, with deficient dynamic fixing or with counterfeit bundling. According to the ongoing WHO appraises, an expected 1 of every 10 restorative items coursing in low-and center salary nations is either unsatisfactory or falsified1

Because of simpler medication access through different channels today, the potential dangers of presentation to fake items has manifolded significantly. Moreover, fake meds have gotten increasingly hard to distinguish as forgers have gotten progressively imaginative in assembling and circulation of phony medications. Such practices are a significant general wellbeing concern, cause huge budgetary misfortune and harm the notoriety of pharmaceutical organizations, dispending drug stores and social insurance experts. The general outcome can be a finished loss of open trust in the medicinal services framework.

A major challenge facing pharmaceutical industries today is the traceability and security of its supply chain, from raw materials to manufacturing and on to the consumer. Although the industry has developed several tracking solutions in the past, such as barcodes or radio-frequency identification (RFID) tags, the problem of counterfeiting continues due to lack of real-time data and inefficient data integration across different suppliers. In India, fake medicines are a major concern with approximately 3% of drugs being substandard or counterfeit, as per National Drug survey 2014-2016, conducted by National Institute of Biologics, Ministry of Health & Family Welfare[2.]

Owing to these factors, the introduction of ‘Blockchain-based solutions’ to the pharmaceutical industry – A decentralized and distributed ledger which will log in data with respect to the individual transactions into a common blockchain, overseen by a Government regulator. This level of monitoring and tracking implies real-time visibility of any tampering or falsifying activities, which can be recorded and rectified immediately.

METHODOLOGY

Key Research Question

How can block-chain based solution be used for tackling counterfeit drugs in India?

Objectives

1. To understand the current scenario of the pharmaceutical market, at a global and National level?
2. To understand counterfeit drugs and their implications in the drug supply chain.
3. To understand the perspectives of each of the stakeholders – Manufactures, Retailers and Pharmacists – around block chain technology.
4. To analyze block-chain based solution and their growing implication in the pharmaceutical industry.
5. Recommendations to develop the way forward.

Research Design

- **Research Design**- Systematic Literature Review

The Indian Pharmaceutical market has been the primary focus of the report; however, the global pharmaceutical market has also been studied to provide a better understanding

- **Data Collection Tool**-
  Literature search across published studies, thought leadership papers, journals, analyst commentary and blogs and news articles were conducted to collate and assimilate the material currently available online to provide a comprehensive understanding of the following parameters:
  a) Counterfeit drugs and their challenges and implications to the broader pharmaceutical market.
  b) Extensive study of the current global and national pharmaceutical landscape.
  c) Detailed examination of pharmaceutical supply chain network and the various stakeholders involved.
  d) Previous 'track and track studies' conducted in India and key finding.
  e) Key Analysis of Blockchain solutions and their growing application in other pharmaceutical avenues.

- **Inclusion Criteria**-
  Any information that evaluated or discussed the issue of substandard or counterfeit medicines in India, as well as the introduction of blockchain-based solutions to counter it.

- **Key words searched**-
  Blockchain, Healthcare, Counterfeiting, Substandard drugs, Pharmaceutical Supply Chain

- **Operational Definition**-
  Counterfeit medicine is the one which is deliberately and fraudulently mislabeled with respect to identity and/or source.

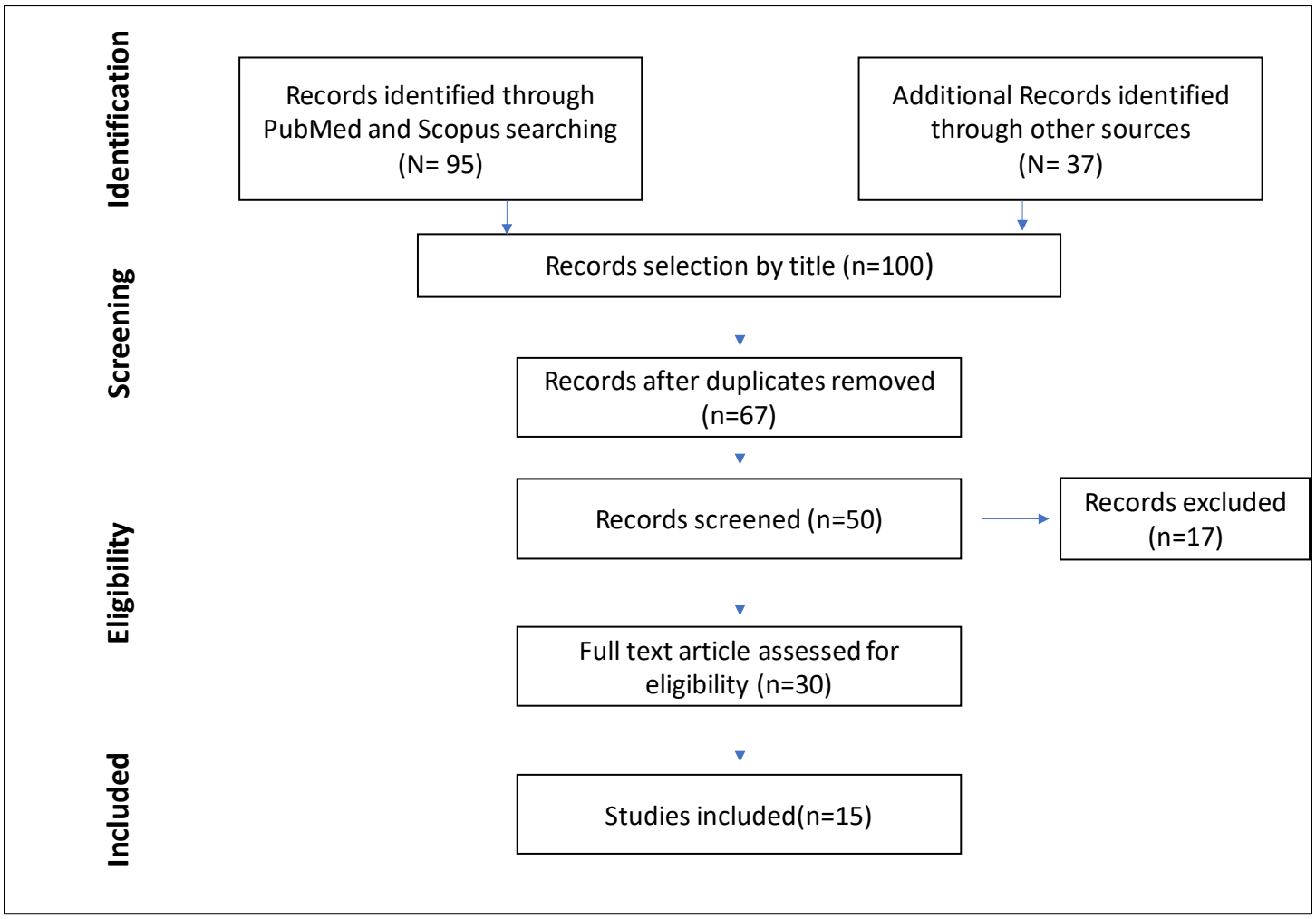


Figure 1 Flow diagram depicting the search process

Current Scenario of Counterfeit Drugs in the Pharmaceutical Drug Market

Overview of Drug Supply Chain

As the Indian pharmaceutical industry is on a growth trajectory, an efficient drug distribution process is of utmost importance. A good distribution process facilitates availability of drugs for not only Metro and Class 1 towns, but also in rural areas. The supply chain in India is highly fragmented. On one side, several pharmacy chains are coming up such as Wellness Forever, Med-plus, Front Line, Apollo, Frank Ross and Roshan. On the other side, e/online pharmacies are gearing up in a big way by luring customers with heavy discounts and cash backs. Some of the popular online pharmacies include 1 MG, Pharm Easy, Med-plus, Net Meds, Myra and Med-life etc.

Touch points in Indian pharmaceutical distribution

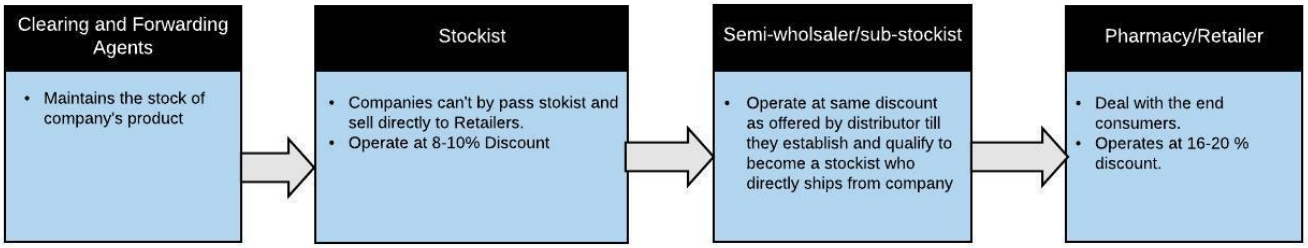


Figure 2- Touch Points in Indian Pharmaceutical Distribution

An illustrative model of the licit and illicit medicine supply chain

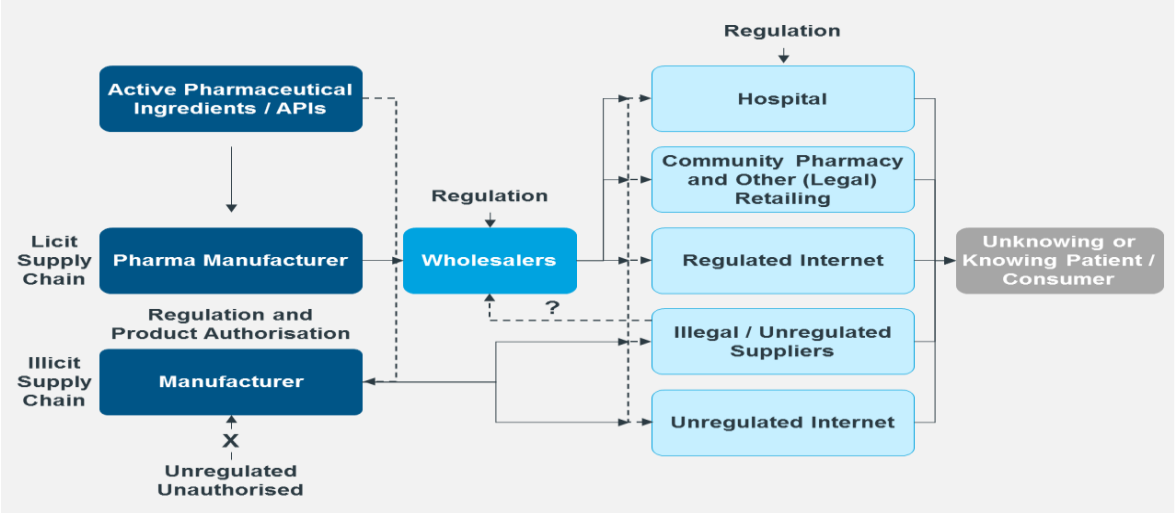


Figure 3 Image Source[3] Licit and Illicit Supply chain

Entry points for counterfeited products:
Much of the time, drugs coming legitimately from the producer's office are reliable. The risk of entry of fake drugs arises when the items are given off between the different stages and layers of the complex supply chain (i.e. wholesalers, distributors, or sub-distributors). At each move point from the plant to the patient, medications can be taken, defiled, and supplanted. The aftereffect of such negligence prompts money-related misfortune to the drug makers, and all the more critically, noteworthy hazard to quiet wellbeing.

Definition of Counterfeit Drugs

Counterfeit drugs are essentially fake medicines that are illegal and pose threat to wellbeing as they may:

- Be adulterated
- Have the wrong or no active constituent
- Have the right active constituent, but in wrong quantity
- Be wrapped in forged packaging, blisters and/or contain falsified patient information
- Have manipulated expiry dates

Unfortunately, it is difficult to make the distinction between a safe and counterfeit drug without a very detailed inspection including appearance, finishing, seal tampering, batch numbers, expiry date, spelling errors and font changes etc. Such microscopic inspection at a large scale is tedious and expensive.

Costly and popularity physician endorsed drugs utilized for Helps or malignant growth treatment are particularly rewarding markets for such organizations. Anti-infection agents, antibodies, erectile brokenness drugs, weight reduction, hormones, analgesics, steroids, antihistamines, antivirals and antianxiety drugs are the most regularly duplicated drugs[4,5]. Crooks exploit the great notoriety of items and brands that the first producer built up through the arrangement of reliably top-notch items. Over the long haul, fakes can debilitate or execute a brand's picture, and an organization's notoriety and possibilities.

This pilot venture means to give provenance and track medicates all through the gracefully chain to take out the section of phony medications in the pharmaceutical flexibly chain. The arrangement proposed will likewise empower temperature consistence all through the gracefully chain to guarantee that end-clients get the medications with dynamic fixings..

Challenges Posed by Counterfeit Drugs

The large counterfeit trade in India has created following challenges:

Consumers: Due to incorrect active ingredients and toxicity there are adverse effects on the consumers such as treatment failure or organ dysfunction. The increased cost of treatment to investigate the complications lead to increase in economic and social burden. Consequently, the consumers might lose confidence in healthcare systems

Industry: The entry of fake drugs in the supply chain and loss of confidence of the consumers lead to loss in business opportunities & market share for genuine manufacturers

Previous Track and Trace Initiatives Done in India

It is a long-held belief that a company should never just use one security technology for its protection, and this is applicable to the pharmaceutical industry as well. So, currently to tackle counterfeiting, many pharma companies use multiple technology layers and platforms on activities such as manufacturing and packaging, routinely changing and restructuring them to reduce the ongoing risk of compromise. Although this is an effective strategy to combat the threat of counterfeit medicines, it could still be very expensive to sustain as it takes millions of dollars to develop and phase out new security technologies at the required pace. Additionally, for most packaging-level security technologies, it is possible to surface a credible counterfeit within six months of deployment[6.]

Other anti-counterfeiting technologies utilized by pharmaceutical companies include holograms, color-shifting inks, bar codes, QR codes, images on packs, and dyes. These anti-counterfeiting features allow pharmacists to identify suspicious drugs as possible counterfeits. Currently, all a consumer can do to reduce the risk of purchasing a fake drug is to insist on a bill and check the batch number and expiry date on both the bill and the drug. However, unless a bill is computerized, it is very easy for a chemist to make the bill non-readable[7.]

The Drugs Technical Advisory Board approved a proposal for a “trace and track” mechanism in which a 14-digit number will be printed on the labels of the top 300 pharmaceutical brands. The numbers will be unique to each strip and bottle sold in the market. The labels will also come printed with a mobile number provided by the company marketing the brand. Patients purchasing these medicines can message this 14-digit number to the contact number provided. They will get details such as the name and address of the manufacturer, batch number, manufacturing date and expiry date. Pharmaceutical companies are still awaiting clarity on how this mechanism will work and who will be responsible for creating the portal that allots the numbers[8.]

National Informatics Centre designed a new system named Drug Authentication and Verification Application (DAVA), based on the GS1 standards, for drug tracking and traceability. The system is based on the use of Global Trade Item Numbers (GTINs) and serial numbers provided by manufacturers for identification of various hierarchy levels for product packaging. The aim is to improve India’s image as a world leader in production of safe pharmaceutical products by providing real-time visibility of drugs produced and exported out of India. The entire DAVA system will be rolled out in phases and will include 2000 manufacturers, beginning with the participation of large and medium manufacturers, followed by small-scale manufacturers. Barcoding at the primary level will be optional, however, barcode labeling and marking at the secondary and tertiary level will be compulsory.

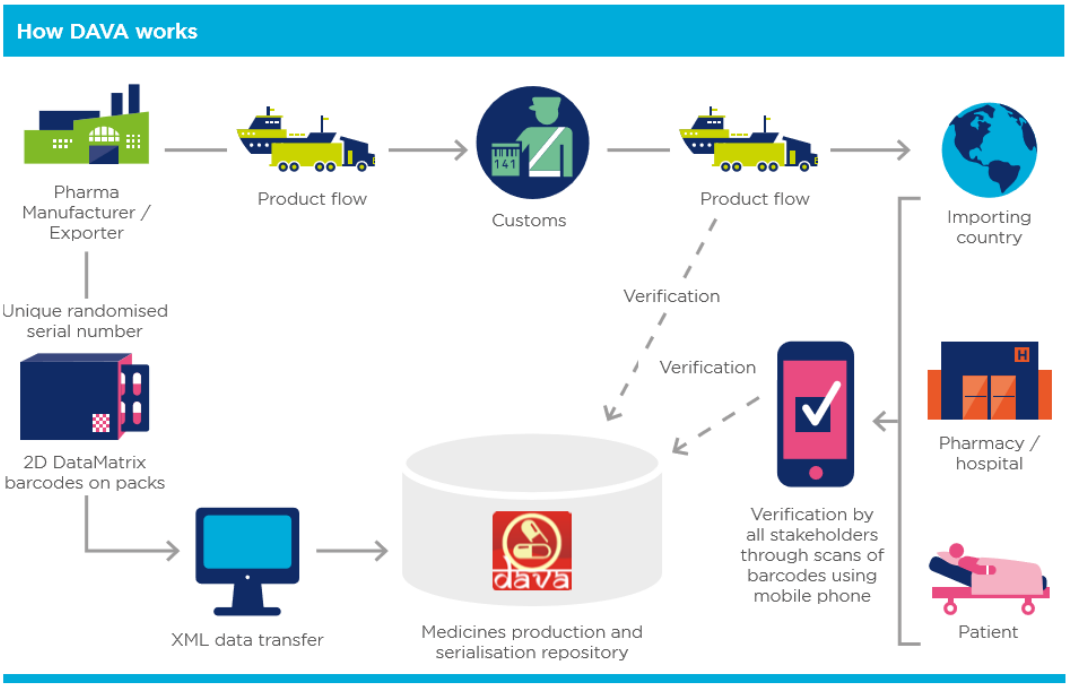


Figure 4 How DAVA works

Image Source[9]

While initiatives like DAVA provide information about products at the manufacturer level, which can be verified by other stakeholders, it does not ensure visibility of each transaction to all stakeholders that is of immense importance in a multi-stakeholder, multi-location and multi-product scenario. Further, it is not able to track and trace the product throughout the supply chain and ensure temperature compliance. With emerging technologies such as Blockchain and Internet of Things (IoT), these can now be achieved.

Blockchain Solving the Problem of Fake Medicines

Blockchain is a decentralized digital ledger that verifies, time stamps and creates blocks of information linked to each other in a fast, secure, and transparent manner using smart contracts. A blockchain based drug supply chain will connect all the supply chain stakeholders including the manufacturer, distributors, pharmacists, and hospitals on a trusted network powered by blockchain. This will create a supply chain network where pharmaceutical Stock Keeping Units (SKUs) are labeled with serial numbers that are scanned and recorded on the blockchain at every point along the supply-chain journey. This process will ensure better compliance and governance within the supply chain by the drug manufacturer.

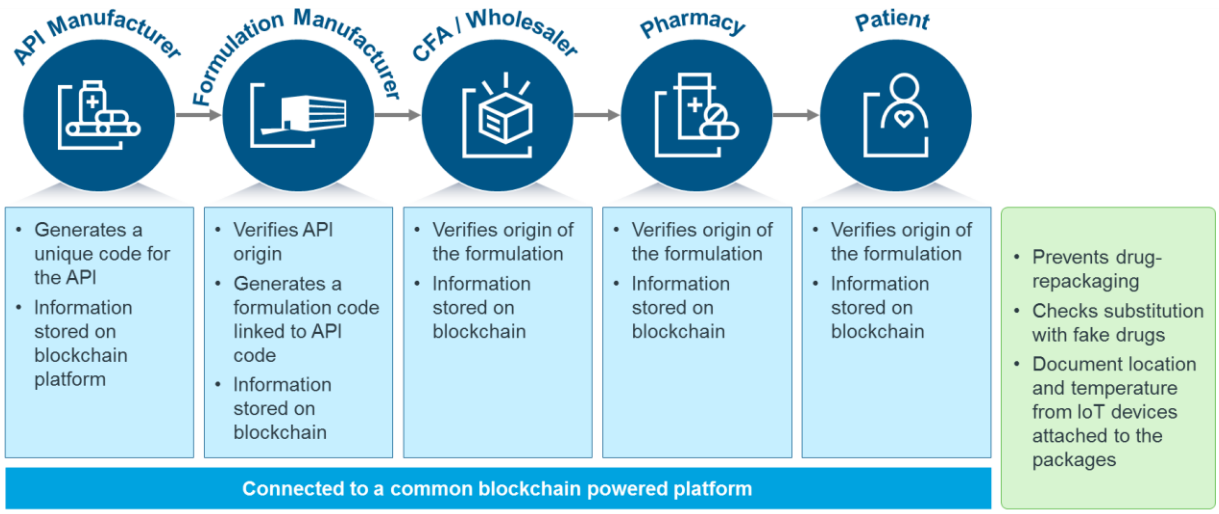


Figure 5 Use of Blockchain across the Pharma Supply Chain to Enhance Traceability

As the pharmaceutical drug moves through the supply chain, each transaction will be pushed by internal systems in an automated manner and will be registered as well as time-stamped using the ledger to ensure security and safety of the product. Due to decentralization, encryption methods and immutable record keeping, a large amount of associated data can be shown to the stakeholders without compromising the data security. Further, even manufacturing inputs, like active pharmaceutical ingredients and excipients can be tracked and linked to the final pharmaceutical products. Additionally, the blockchain can document critical details like location and temperature from IoT devices attached to the packages, making the journey visible to all stakeholders, thereby limiting the possibility of record tampering. The introduction of blockchain technology in the supply chain will enable pharma companies to reduce dependence on intermediaries, ensure transparency in stock movement, control quality, and improve overall reputation of the industry.

There has been a growing interest in the application of blockchain technology across the industry, proven by a recent survey conducted by the non-profit organization, Pistoia Alliance in 2018. The survey of 170 life science and pharmaceutical professionals revealed that 60% had a keen interest in blockchain technology as compared to 22% in 2017. Among those that were exploring opportunities, 30% focused on significance of the technology in the supply chain, 25% for digital medical records, 20% for clinical trial management and 15% for scientific data sharing. This survey is just one example of the numerous studies that reflect the industries rising interest in availing the opportunities provided by blockchain technology in relation to the pharmaceutical supply chain[10]

Resistance to Implement Blockchain in Healthcare

While blockchain based solutions offer immense potential to reduce the supply of counterfeit drugs, companies and regulators have apprehensions around successful, large-scale implementation of the technology.

Resistance to adopting a blockchain based technology is particularly high due to:

- Difficulty in choosing the right blockchain partner who has a proven track record of working with and implementing blockchain. This is essential for smooth incorporation of the technology in the existing supply chain processes.
- Limited knowledge about the working and transformation requirements for seamless integration with existing IT Networks and benefits about blockchain technology. This is because blockchain technology is in its early stages of development and the benefits are currently probabilistic in nature.
- High aggregate cost associated with incorporation of blockchain technology in the existing supply chain processes.
- No regulatory obligations to be fulfilled, as the current rules does not mandate the use of blockchain technology by either the government or the industry**.** For example, the Drugs and Cosmetics Act, 1940 and Rules, 1945 does not yet necessitate GS1 labelling in addition to standard labelling of drugs imported and manufactured in India.
- Difficulty in sourcing the right talent to build and run blockchain based solutions and the burden of training the workers who will be executing the activities required for successful tracking and tracing of the drugs.
- Potential exploitation of the blockchain technology due to a security flaw (e.g., 51% attack - assault on blockchain by a gathering of diggers controlling over half of the network\'s mining hash rate)[11]

Recommendations

Key Steps Proposed for Adoption of Blockchain Technology

Establishment of a Governance Framework

At the nascent stage that we are at managing counterfeiting in India, an inclusive approach is required which provides policy definition, awareness, technology-based implementation across the pharma value chain and programme monitoring and vigilance to curtail leakages in the system. Therefore, at a broad level, any framework to curtail the counterfeiting nuance should cover the aspects of policy and regulation, technology and implementation, and monitoring and vigilance as detailed further within the section.

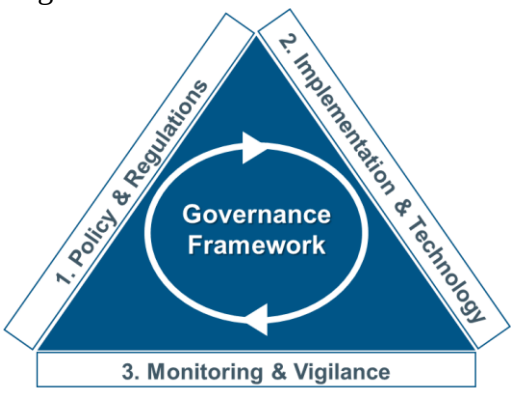


Figure 6 Framework of Governance

1. **Policy and Regulations**

Develop new and amend existing anti-counterfeiting mechanisms

At the policy and regulation level, the immediate aim for the government should be to amend current policy and ensure stricter enforcement of existing anti-counterfeiting mechanisms that aim to:

- Improve the identification of medicines and enable tracking and tracing
- Prevent entry of counterfeit medicines at both API and formulation levels in the value chain
- Prevent the sale of counterfeit medicines at any dispensing channels, such as hospitals, dispensing doctors, retail pharmacies or wholesalers, or though e-pharmacies

In the long term, new policies and acts need to be developed to cope with a fast-changing environment where it has become increasingly important to manage digital interventions and physical traceability of medicines, without hampering businesses that operate in a highly regulated industry.

Leverage global anti-counterfeiting policies & regulations for customization to national context

At a principle level, policy development should incorporate the following considerations:

- **Control of the vulnerable entry points in the distribution chain for counterfeit medicines:** Across many countries, specifically highly regulated ones, there are specific laws and acts to take control counterfeit entry points. The table below lists specific acts that the US has instituted and implemented

Title	Purpose	Description
Prescription Drug Marketing Act of 1987 (PDMA)	To prevent wholesale drug diversion	It requires state licensure of prescription drug wholesalers, regulates drug distribution and bans reimportation of drugs except when done by the manufacturer. This act also requires the purchaser must be provided with pedigree information which contains information about all parties involved in the transaction, date of each prior transaction and information about the drug.
Reducing Fraudulent and Imitation Drugs Act of 2006	To improve identity detection of drug products	It requires the use of radio frequency identification (RFID) or other track-and-trace technology, blister packaging and tamper-indicating technologies into the packaging of any drug.
Creation of the Food and Drug Administration (FDA) Counterfeit Drug Task Force	To lead in anti-counterfeiting actions	It covers reporting of suspected cases to FDA's Med Watch System; This system provides the public and all stakeholders easily accessible information regarding SSFFC and safety alerts regarding medicines..It established the Counterfeit Alert Network (Ziance, 2013). This sustains the flow of communication among government and non-government stakeholders.
Ryan Haight Online Pharmacy Consumer Protection Act of 2008	To protect public from counterfeit medicines sold through the internet	It prohibits the delivery, distribution, or dispensing of controlled substances over the internet without a prescription (Chambliss, et al., 2010). The Act required the accreditation on online pharmacies to be differentiated from those who have not met government requirements for accreditation.
Adoption of the *Normal Distribution Model* for wholesale distribution by 18 States	To prevent entry of counterfeit prescription drugs	The wholesaler purchases prescription medicines solely from the manufacturer or designated agent of that manufacturer as required by law. If not, a documentation known as a pedigree has to be given to the buyer.

**Source: https://www.who.int/medicines/areas/coordination/SSFFC_Report.pdf*

- **Provide data protection and information security protocols:**
  Policies and acts should include provisions that guide information security protocols to be followed by the industry and the channel, while also driving adoption of harmonized standards. Encryption capability built on top of the blockchain solution while transmitting data through robust protocols such as ZKP systems could form one of the options.
- **Choice of platforms:**
  While the underlying technology may be blockchain driven, policies should grant flexibility in the choice of platforms chosen by stakeholders
- **SOPs and benefits to the value chain stakeholders:**
  The policy should outline appropriate benefits for early implementation as well as penalty for lapses and defaults in implementation, giving a suitable time window to the stakeholders. The benefits may relate to tax benefits or other SOPs, while penalties may include restrictions on distribution and sale of non-compliant products

Key action areas for anti-counterfeiting policies and regulations for the industry and government

- **Outline stakeholder ownership rights**

Ownership of the track and trace mechanism (such as bar code or a QR Code) needs to be established. To establish ownership rights, the following two wo models could be suggested:

- *Provision of barcode/QR code ownership to the regulator*: where each manufacturer will need to register details with the regulator to get the code issued and would then have this code mandated to be printed as label requirements at SKU level (which would also need amendments to the relevant sections of the drugs and cosmetics act defining the labeling requirements)

a. This may evolve from manufacturer code to begin with in the first phase and extend to include further details like batch codes, manufacturing entity, and drug information

- *Provision of barcode/QR code ownership to the drug manufacturers*: that will create a repository of such codes with the regulator, where the implementation may be channelized in the same way as mentioned above

- **Establish a mandate for unique barcoding**

  At present following is executed uniquely for traded drugs. On tenth January 2011, Directorate General of Outside Exchange gave rules for the Usage of a track and follow framework consolidating standardized tag innovation according to GS1 principles for all medications and pharmaceutical items traded from India. All fare pharmaceutical transfers ought to be checked and coded at different bundling levels utilizing GS1 standardized identification standards[12].

  In 2015, another draft note was given by the Association Wellbeing Clergyman, which expressed that all the local medication makers must guarantee that medication strips have a 2D/3D scanner tag on the bundling names, which can be followed and followed by a focal entrance framework. Notwithstanding, no firm date or schedule was set up for a reception of the residential guidelines.

  A uniform law is subsequently necessitated that orders the utilization of GS1 scanner tag on every single saleable medication that are fabricated and imported to India. These bar-coding prerequisites will apply notwithstanding standard marking necessity under Medications and Makeup Act, 1940 and Rules, 1945. Further the Service of Trade ought to characterize and build up the system for joining special barcoding and a cutoff time for turn out ought to be chosen.

- **Conduct cost revisions to facilitate unique barcoding**

In the past, small and medium enterprises have expressed their reluctance towards incorporation of unique barcodes owning to the additional cost of 6 paise per strip to print the unique identity number and setting up of separate software systems at each production line[13]. In addition, the price ceiling introduced by the government in public interest restricts their bandwidth to increase their costs. Further, the benefits of the proposed technology are currently probabilistic in nature. Hence early adopters may feel that marginal utility is less, and risk associated is high. Therefore, the government needs to ensure that the cost of compliance is reduced. One such possibility could be to raise the price ceiling to a point that balances both business and public interests.

- **Establish standards for drugs needing temperature-controlled logistics**

In the current scenario, most of the carriers and warehouses don't follow required temperature for the drugs. Cold chain drug requires 2-8 degree as against normal that can transit in 28 degrees. Hence use of IoT enabled devices would ensure that temperature sensitive medicines are dealt with utmost care. While there are defined standards for drugs like injectables during manufacturing and storage that are generally followed, there may be variances beyond guidelines in-transit. Such standards would require to be established for in-transit period both with respect to limits to temperature variances and the duration for which such a variance could be acceptable. Such initiatives are today trackable given the IoT based temperature sensing technologies as outlined in this report. However, these limits would require to be established via determination of clinical effectiveness in the suggested tolerance limits of temperature and time frame of exposure via additional testing

in controlled lab environment. These deviations may differ from product to product within injectables/biologics/biosimilars and by other dosage forms such as tablets (which may be relatively less sensitive and therefore could have wider tolerance limits). Essentially this would be a step towards provisions to enforce temperature standards (especially for carriers and distributors of cold-chain drug) during drug transit to ensure delivery of effective drugs.

- **Develop and enforce security measures that prevent data leakages/tampering**

Information flow and security through the supply chain ecosystem (Regulator-Manufacturer-Distributor-Retailer-Consumer) needs to be ensured. A framework needs to be established for the norms of information availability for each stakeholder and maintenance of an audit trail.

A robust and seamless process definition will also be required to make the entire system seamless and information to be translatable from one system to another, as the information flows from one stakeholder system to another, e.g. from a manufacturers ERP system directly to a blockchain based track and trace platform when a drug consignment is ready to be shipped to the next entity and so on.

The government needs to ensure and give confidence to the stakeholders that the proposed technology will be security proof. The stakeholders may not be willing to share data in a network that contains their competitors. Any leak about their costs/sales will have major repercussions on their business. Therefore, the government may propose following data sharing concepts:

- Zero knowledge proof can be used that allows verification without revealing additional information
- Asymmetrical cryptography can be proposed to prevent hacking. It uses a pair of keys, one for encryption and one for decryption. While all knows the public key, only the owner knows private key. Prior to the transaction, there is no need to exchange private keys

The stakeholders need to be assured about the intent of the government in introducing the technology for the overall benefit of the industry and consumers rather than policing the industry

- **Prevention of data leakages/tampering at stakeholder level**

At the partners' level, pharmaceutical organizations must put resources into a confided in accomplice, who sees all the subtleties of the global scene and has important enlistments, assets, innovation and procedures set up. It is important to engineer a long-term solution that can withstand any tampering of real time data captured by IoT platform.

While the discussed policy-based recommendations and corresponding implementation will be important, the true benefit of such a system will accrue only if it is used at large, especially by the consumers to validate the purchase. Additional push will be required at the consumer level by way of awareness building initiatives, whether by the government or through stakeholders in the distribution channels.

2. Implementation & Technology

Formation of a government-led public-private stakeholder consortium for advocacy

At each step of the value chain there are multiple stakeholders, associations and consortia (such as the OPPI, IDMA, AIOCD, among many others) that need to be aligned on every aspect of the policy as an ongoing task until everyone comes onboard. One of the possibilities is to set up a government led consortium of policymakers with fair representation of all the private stakeholders to onboard the highly fragmented value chain, define the governance framework.

Provision of non-editable, track and trace records may present a challenge to the acceptability of the technology as all information is shared through the channel (at least on volumes) for every manufacturer/marketer. Such granular level of data sharing could become liable to hacks and information

leakage about the business itself and can subject any manufacturer to an audit trail at any point in time. However, a government led consortium will be a good model to give visibility to the use cases that might encourage stakeholders and increase their trust in the system.

Deploy a phase-wise implementation approach

The Indian Pharmaceutical market is highly fragmented with multiple stakeholder involvement, hence bringing everyone onboard at the same time and on the same technology platform may emerge as a daunting challenge. Therefore, the governance framework will need to establish the most important stakeholders to initiate a phase-based implementation and gradually bring on the remaining members to minimize disruption. Guidelines and SOPs may be drafted by the government for each stakeholder to ensure transition into the new system. Further, selection of a blockchain technology will bring with it the benefit of being a distributed ledger system that would need to be rolled out in phases to avoid large-scale disruption, misalignment of stakeholders and use of ineffective vigilance and monitoring channels.

Infrastructural support from chosen technology provider (public, private or PPP)

Development, ownership and implementation of blockchain technology might be driven through a public-private partnership. A phase-based approach would ease the implementation process as in many cases the process would need to be initiated from ground level through the provision of basic infrastructure before other technological interventions are considered. In such cases, the key infrastructural considerations for the technological provider, irrespective of being a public, private or PPP entity would include:

- Provision of a system that can verify and validate transactions at last stage on supply chain, in the absence of smartphones. The usage rate of smartphones is low, especially in rural areas. Hence there should be a mechanism to authenticate the drug via SMS (USSD code) against SMPP system.
- Seamless online integration of the data is necessary at each interface to achieve the required result. Example - Manufacturer should be able to push data from their ERP system directly to the Blockchain when a drug consignment is ready (Delivery Note is generated) to be shipped to the next entity.
- Requirement for the chosen technology to be equipped with battery backup to have the data during power outages as well. There is a need to have a provision of offline updates to the IoT device, in case of non-availability of internet for transmission. The stakeholders should choose right sensors that support range and accuracy required to monitor the drugs in the supply chain.

Technological needs and usability of each value chain stakeholders will be different, leading to difference in the platform choice and scale (e.g. the needs for a manufacturer will be different from that of a retailer). The implementation may be smoother if the new technology is enabled to ride on the existing technology/systems/platforms being currently used be these stakeholders (like SAP being used by manufacturers and MARG/Tally being used by Distributors or Retailers as well).

The details in which the track and trace system is envisioned, such as authentication of the drug itself or based on other parameters like temperature/humidity or other environmental parameters would require the use of technologies such as appropriate sensors and IoT based platforms. Such capabilities may be brought under the policy in subsequent phases of amendments and later as implementation once the new system stabilizes.

3. Monitoring and Vigilance

Design effective monitoring & vigilance systems to improve practice and ensure accountability

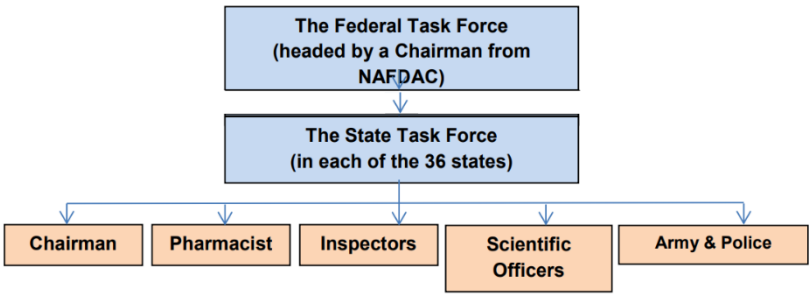
As observed time and again, any policy, however detailed and all-encompassing at the formulation stage, is liable to workarounds being exploited. A well formulated technology focused policy, even if implemented

well, would still need monitoring due to the dynamism of technology itself or from an evolving industry or business landscape standpoint. This makes it important to continuously monitor the post implementation phase and create relevant KPIs for different stakeholders. While monitoring is important, vigilance is another aspect that should be provisioned as the policy is formulated and implemented.
Vigilance is important to successfully plug the loopholes identified while monitoring progress. For example, tracking upstream to identify the source of counterfeiting is important to put a stop on the unethical process. The upstream tracking is likely to be challenging as such drugs would be inherently outside the blockchain technology network, hence difficult to trace. Such situations illustrate the importance of a vigilance system to be set up, whether through existing law enforcement agencies or establishing a separate task force to curb this menace.

Leverage global examples of successful vigilance systems for customization to national context
In more regulated markets there are systems and networks of different groups focusing on monitoring and vigilance,[14] for example some efforts in the US include:

- The FDA's Counterfeit Alert Network (CAN) which develops and disseminates information on counterfeit drug incidents in the US and control measures taken. In addition, it is responsible for the formation of a network including national organizations, consumer groups and industry representatives for distribution of the information.
- MedWatch which is an FDA provided internet-based reporting system for serious problems encountered with medical products and it is also a source of safety alerts regarding medicines.
- SAFE DRUG checklist formulated by The Partnership for Safe Medicines to help consumers identify and protect against counterfeits and the SafeMeds Alert System which informs enrollees about counterfeit alerts announced by FDA and other health agencies.

There are several country examples where as part of strengthening the vigilance systems, multi-stakeholder task force systems have been created to ensure curb on counterfeiting medicines. One of these is the Nigerian Task Force33, which is the enforcement arm of the National Agency of Food and Drug Administration and Control (NAFDAC) and is divided into two classes: The Federal Task Force and the State Task Force, as represented in the figure below:

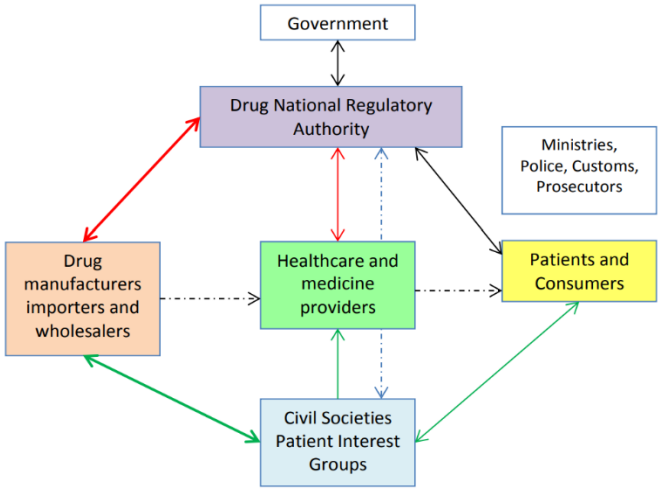


Both the Federal and State teams are subsidized by the Ministry of Health and are empowered to close all unregistered premises until fake medicines are expelled or upon the request of the Minister of Health. The significant exercises of the task forces are:

- To lead assaults in a joint effort with NAFDAC authorities, an agent from the Pharmaceutical Society of Nigeria and Pharmacists Council of Nigeria, authorities of the State Ministry of Health that include a legal officer, and a public relations police officer.
- To teach people in general through public awareness and enlightenment campaigns on the risks of counterfeit medicines and to decrease demand for these medicines. The teams conduct post-marketing

surveillance through routine and surprise inspections, and investigation upon receiving consumer complaints. In conducting inspections and raids, a pharmacist must be present. The senior pharmacist acts as the team leader

In Indonesia there are laws and rules controlling fake meds, for example, the Law No. 23 on Wellbeing (1992); Law No. 8 on Consumer Protection (1999); Law No. 14 on Patent (2001); and Law No. 15 on Trademark (2001), in spite of which duplicating is common. To address the recently referenced components, a participation of a few partners was set up by the administration. In this model, social insurance suppliers are at the inside and they work together with government offices, privately owned businesses and even with patients and buyer gatherings. At the point when fake prescriptions are accounted for to have entered the gracefully chain, the police and NADFC perform attacks to hold onto these drugs. Prepared monitors and specialists direct examination on presumed meds. Organizations with law authorization offices, both national and universal are created to impact customer request. Open mindfulness is additionally raised through leaflets and TV ads.



Indonesia's Mechanism of National Coordination (NADFC, 2007)

The implementation of such frameworks across countries have led to a reduction in counterfeiting. However, the mentioned strategies are likely to be more successful when there is a strict regulation, and in many cases a punitive stance taken by the government. In conclusion, a well-planned integration of blockchain with the existing system will provide many benefits for the sector and national economy at large.

Way Forward

Blockchain Technology – Catalyst for Change

Blockchain Technology in Pharmaceutical sector will be a step forward to empower the end-consumers. The consumers would be able to verify if a drug being consumed is fake or correct through their respective mobile phones. On a larger scale, incorporation of technology in true spirit in pharmaceutical sector is in public interest and would improve health outcomes in India. In addition, blockchain technology would ensure transparency and operational efficiency as well as prevent business loss to counterfeit drugs

Even though blockchain can possibly convey generous advantages and investment funds by improving operational effectiveness and by altogether diminishing exchange costs, extensive difficulties must be defeated before the innovation can accomplish standard reception in the pharmaceutical flexibly chain industry. Picking up industry selection is of most extreme significance and will decide the achievement of blockchain innovation in this field. In the coordination's business, which is described by a gracefully chain condition with various partners, having the option to precisely and securely trade data is a key preferred position. The innovation itself, just as utilizing on-screen characters, benefits the most when their locale contains numerous pertinent individuals. Truth be told, a ground-breaking system impact is possibly activated when partner selection arrives at a minimum amount, transforming blockchain into an acknowledged industry practice. Be that as it may, it will be troublesome from the outset to get partner responsibility in light of varying degrees of computerized status and the underlying prerequisite to perceive the common advantages of blockchain-based joint effort.

A few industry specialists accept that at this phase of improvement a blockchain arrangement won't really dislodge existing programming, yet rather will enlarge it. For an industry with a few advanced medications, for example, biologics, which are costly to create and require explicit techniques for transport, this extra degree of detail can give an additional layer of security and understanding. In the event that there is a disappointment in the flexibly chain which impacts the medication, through blockchain and a more extensive Web of Things framework, the specific issue can be pinpointed, possibly continuously and address it.

The buyers would should be educated about the advantages of the proposed innovation and their capacity to check the medications they are expending for anticipation or treatment purposes. To guarantee that all the customers check before utilization, the data should be made accessible on mobiles/stages available by all the people.

As examined in the prior segments, blockchain offers the capacity to follow and question the birthplace of a medication (or dynamic pharmaceutical fixings), just as track its movement all through the whole flexibly chain. This would give expanded brand insurance through avoidance or quick response to assembling surrenders. Past item uprightness and against falsifying endeavors, blockchain could likewise assume a job in beating the budgetary difficulties looked by littler administrators along the flexibly chain, a continuous issue in creating nations, for example, India, wherein tranquilize gracefully chains are regularly significantly more divided, with many organizations each taking a little portion of the market. Besides, the involvement in blockchain in different businesses, remarkably food, have just shown the capability of blockchain innovation to address difficulties in gracefully chain the executives. Along these lines, there is a more extensive guarantee and capability of blockchain, which can in a general sense change organization by dispensing with wasteful aspects, accelerating exchanges and empowering creative plans of action.

With progress being seen across different enterprises and guidelines requiring more prominent network and oversight for the pharmaceutical gracefully, it may not be long until blockchain turns into a principal part of the flexibly chain.

While the integration of such a technology continues to be cumbersome, and costly, it's in the best interests of public health in the long run. Therefore, all the involved stakeholders must battle the menace of substandard drugs together and help in making the drug supply chain a full proof mechanism. With the widespread adoption of blockchain technology, the real value in the industry is expected to come from working on a common platform to provide true interoperable capabilities that never existed before.

Blockchain can help improve the productivity of conveying a sheltered and viable medication to patients and in general, build up a more grounded establishment of trust in the pharmaceutical business, who lately has been attempting to keep up its notoriety with patients as the end customers.

With the advent of blockchain based solutions, the pharmaceutical industry is at the brink of a nation-wide transformation. Going forward blockchain technology could also be used to give visibility to all the stakeholders and consumers about the ingredients being used in the making of the drug. It is hoped that blockchain would revolutionize the pharmaceutical supply chain by enabling a simple single use system for all stakeholders including consumers, giving transparency, security and oversight of the end to end delivery of drugs

DISCUSSION

Counterfeiting today is a global issue. There is no single country, which can deter the existence of counterfeit drugs in its pharmaceutical market. Countering the existence of such falsified or substandard medicines require collaboration at national, regional and international levels between the law providers, enforcement agencies, manufacturers, suppliers and consumers.

Additionally, successful implementation of blockchain technology will require a thorough business review to understand preparedness to adopt blockchain. Since blockchain is an intensive play of complex data, supply chain players will have to automate their respective technologies to aid in seamless integration of information. Stakeholders will have to embrace a culture of acceptance and standardization for its effective implementation.

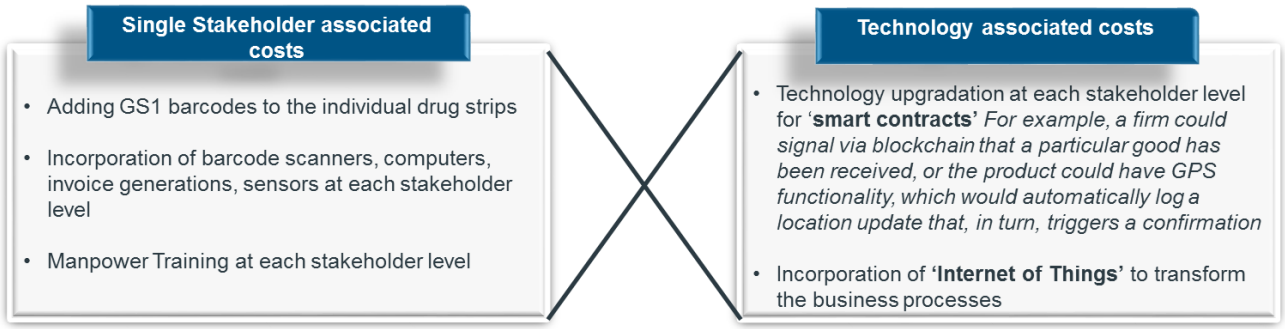
Important Factors to Consider

Importance of seamless coordination between stakeholders

It is necessary to develop and enforce appropriate standardized mechanisms of effective collaboration between various stakeholders such as health authorities, police, customs, the judiciary, manufacturers, wholesalers, retailers, health professionals and consumers. There is a need of systemic training for all the stakeholders involved, to help in verifying and reporting falsified drugs. The initiative must be broadcasted and advertised to ensure the involvement of all the stakeholders. There must be proactive push by the health practitioners to educate the masses regarding the harmful impact of succumbing to counterfeit drugs, and the incentive to report such cases effectively.

- **Understanding the costs and benefits associated**

Currently the Indian pharmaceutical industry is valued at $15.52 Bn (as of January 2019)[15]. With the adoption of blockchain technology, the industry is expected to save about $0.45 Bn that is lost due to counterfeit practices.



Blockchain applications in the gracefully anchor the executives is required to give a relative favorable position dependent on unchanging nature, straightforwardness, and decentralization, which are likewise intrinsic highlights of the innovation. Furthermore, it likewise gives access to significant information since the data is put away over a few PCs and systems giving a protected, copied, and synchronized uniform record, i.e., for advanced bills of filling which can't be furtively. For instance, computerized bills of filling would encourage to accelerate current procedures and to diminish cost, as they take into account the end or decrease of desk work related with the present strategic policies.

Furthermore, a selection of the innovation would improve the administration of as of now lumbering authoritative desk work, as transfer approval and control as of now are tedious and incorporate the possibility of human mistake influencing the procedure. Moreover, at present, the data is regularly constrained to timestamps of when the medication bundle enters the wholesaler/retailer's taking care of framework. Enlisting

a bundle on the blockchain would consider following the developments all through the gracefully chain and addition progressively exact data with respect to the hour of conveyance

In addition, the capacity to follow the starting points of medications or its course of flexibly in current coordination's framework is somewhat restricted. The blockchain gives a protected stage to all the worth chain suppliers to share and trade data concerning their merchandise and items. The capacity to share data and to demonstrate to buyers that their items begin from protected and maintainable makers could build client unwaveringness and, thus, gainfulness.

The cost investment funds coming from potential blockchain arrangements are moderately simple to speculate and evaluate by contrasting them with reference costs related with current business forms. Cost reserve funds will rise up out of mechanization and effectiveness gains as regulatory and transparency issues get addressed.[16] IP concerns from India have been voiced in the past by the USTR such as the lack of transparency of information on pharmaceutical manufacturing licenses issues by the state, loss of business etc[17.] The adoption of blockchain technology will ensure that global concerns on the subject are met as:

i. Licensed manufacturers will need to share the relevant license documents in blockchain among stakeholders to ensure transparency about provenance, route and licenses
ii. The use of blockchain and IoT will make it difficult for a fake drug to enter the supply chain as a package is getting tracked throughout the chain and checked at every node. Hence this technology ensures that business is not lost to fake dealers. Therefore, the Indian government will be able to track unauthorized market players and take suitable actions to ensure aid in law enforcement.

Bibliography

1. World Health Organization, 1 in 10 medical products in developing countries is substandard or falsified, November 2017. Available online: https://www.who.int/news-room/detail/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified
2. Survey of Extent of Problems of Spurious and Not of Standard Quality Drugs in the Country, 2014-2016, National Institute of Biologics, Ministry of Health & Family Welfare. Available online: http://www.indiaenvironmentportal.org.in/files/file/National%20Drug%20Survey%202014-16.pdf
3. Dr. Usman Kahn et al, Falsified Medicines and the Global Public's Health, May 2011. Available online: https://www.ifpma.org/wp-content/uploads/2016/01/UCL-Matrix_Insight-Falsified_Medicines_and_the_Global_Publics_Health.pdf
4. Food and Drug Administration. Reporting serious problems to FDA. www.fda.gov/Safety/MedWatch/HowToReport/default.htm, January 6, 2011. Accessed March 29, 2014.
5. Chambliss WG, Carroll WA, Kennedy D, et al. Role of the pharmacist in preventing distribution of counterfeit medications. *J Am Pharm Assoc (2003)*. 2012;52(2):195-199. doi:10.1331/JAPhA.2012.11085
6. Meg Snyder, Keeping Counterfeit Medicines out of the supply chain, January 2016. Available online: https://www.pharmaceuticalprocessingworld.com/keeping-counterfeit-medicines-out-of-the-supply-chain/
7. Ashima G. Siraj, Pharma Secure: Fighting fake drugs in India, August 2012.
8. Central Drugs Standard Control Organization (CDSCO), Minutes of the 79th Meeting of Drugs Technical Advisory Board, May 2018. Available online: https://www.cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCommitteeFiles/79thDTAB.pdf
9. GS1 India, Drug Authentication and Verification Application Available online: https://www.gs1india.org/content/dava1
10. David Proudlock. Pistoia Alliance, More Than Half of Life Science Organizations Already Using or Experimenting with Blockchain, up from Less Than a Quarter in 2017. September 27, 2018. Available online: https://www.pistoiaalliance.org/news/more-than-half-of-life-science-organisations-already-using-or-experimenting-with-blockchain-up-from-less-than-a-quarter-in-2017/
11. Deloitte, Blockchain Enigma. Paradox. Opportunity, 2016. Available online: https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/Innovation/deloitte-uk-blockchain-full-report.pdf
12. M G Moniveena, T M Pramod Kumar, An Overview of Track & Trace Regulations in Pharma Industry and its Impact on the Reverse Logistics of Medicines- Status in Regulated Countries and India, December 2017 http://globalresearchonline.net/journalcontents/v47-2/16.pdf
13. New Bar-Coding Rule May Crimp Pharma Margins, Business Television India, Jul 2015
14. Robles YR, Casauay JF, Bulatao BP. Addressing the barriers to effective monitoring, reporting and containment of Spurious/Substandard/Falsely-labelled/Falsified/Counterfeit medical products through sustainable multi-stakeholder collaboration and community/consumer-based interventions. Medicines Transparency Alliance, Manila. 2015.
15. Indian Pharmaceutical Industry, India Brand Equity Foundation, April 2019
16. Dobrovnik M, Herold DM, Fürst E, Kummer S. Blockchain for and in Logistics: What to Adopt and Where to Start. Logistics. 2018 Sep;2(3):18.
17. Office of the United States Trade Representative, Special 301 Report, 2018 Available online: https://ustr.gov/sites/default/files/files/Press/Reports/2018%20Special%20301.pdf

ANNEXURES

Appendix

Points to consider for barcoding for the new barcode users, as per GS1 benchmark –

1. Get a GS1 Organization Prefix

- Before an organization can start utilizing scanner tags, they should initially relegate the numbers that go inside the standardized tag, called GS1 Distinguishing proof Keys. The initial phase in relegating a GS1 ID Key is to get a GS1 Organization Prefix from a GS1 Part Association. The GS1 Organization Prefix gives an approach to organizations to make distinguishing proof keys for exchange things, calculated units, areas, parties, resources, coupons, and so forth which are extraordinary all around the globe

2. Assign numbers

- After getting a GS1 Organization Prefix, an organization is prepared to start doling out ID numbers to their exchange things (items or administrations), themselves (as a legitimate element), areas, calculated units, singular organization resources, returnable resources (beds, barrels, tubs), and additionally administration connections

3. Select a scanner tag printing process

- To start, it is critical to choose the sort of barcoding that the maker is searching for and if the scanner tag will convey static or dynamic data inside it. On the off chance that the data is static (consistently the equivalent), the standardized identification can be printed utilizing conventional print machines legitimately on the bundle (e.g., paper milk container) or on a name that is applied to the bundle (e.g., mark on a gallon milk container.)

4. Select a \"primary\" checking condition

- The determinations for scanner tag type, size, arrangement, and quality all rely upon where the standardized identification will be filtered. By knowing where your scanner tag will be checked you can set up the correct determinations for its creation.
- Barcodes to be filtered at the retail location should bolster omnidirectional checking. On the off chance that the standardized identification will be checked at retail location just as in the stockroom, you should utilize an image that suits retail location filtering however imprinted in a bigger size to oblige examining in the dispersion procedure.
- Barcodes on medicinal services things to be filtered in clinics and drug stores don't require omnidirectional examining, except if the things are additionally checked at retail location

5. Select a standardized identification

- Selecting the privilege standardized identification is basic to the accomplishment of your scanner tag usage plan
- If the producer needs to encode a URL into a scanner tag to make stretched out bundling data accessible to the end shopper, at that point you should utilize a GS1 2D image

6. Pick a scanner tag size

- After the right scanner tag image is determined along with the data to encode in it, the plan stage starts. The size of the image inside the structure will rely upon the image determined, where the image will be utilized, and how the image will be printed

7. Format the standardized tag content

- The message underneath a standardized tag, called Intelligible Understanding (HRI), is significant in such a case that the scanner tag is harmed or of low quality in any case, at that point the content is utilized as a back-up.

8. Pick a standardized identification shading - GS1 scanner tags require dull hues for bars

9. Pick the standardized identification arrangement

While talking about image area, we are alluding to the image arrangement on the plan.

- When allocating image arrangement first the bundling procedure ought to be thought of. You ought to counsel the bundling specialist to ensure the image won't be darkened or harmed (e.g., over a container edge, underneath a container crease, underneath a bundle fold, or secured by another bundling layer).
- After deciding the correct situation, the printing organization ought to be counseled. This is on the grounds that many printing forms require standardized tags to be imprinted in a particular direction to the feed heading of the web or sheet.
- When utilizing flexographic printing the bars should run corresponding to the press bearing. On the off chance that the bars are required to run opposite to the press bearing check to guarantee the image isn't contorted.

10. Build a standardized identification quality arrangement

GS1 utilizes the ISO/IEC method, but specifies the minimum grade necessary for every GS1 barcode based on which symbol is used, where it is used, or what identification number it is carrying. In addition to the minimum grade, GS1 also specifies the verifier aperture width and wavelength

Following links can be accessed for further information regarding the GS1 standards for barcoding –

- MSO - http://dghs.gov.in/WriteReadData/Tender/20180620045349892758TE03.pdf
- DGFT – http://dava.gov.in/davanew/files/PublicNotice_01_Nov_2018.pdf
- DGFT - http://dava.gov.in/davanew/files/PublicNotice_05_2016.pdf
- MOHFW - https://indiacode.nic.in/ViewFileUploaded?path=AC_CEN_12_13_00023_194023_1523353460112/notificationindividualfile/&file=10.GSR+381%28E%29+dated+18_04_2018.pdf
- Chhattisgarh - http://www.cgmsc.gov.in/Upload/BANDAGE%20TENDER201903000001.pdf
- Punjab - http://www.punjabhealth.co.in/downloads.aspx?ID=M0R1Aud8JSQ%3d&&Header=r317PCRsFDgTXOWiEeKbmTc2p2aRPbfZOvk2ScXCdF0THZ3gxMZMb2mvrC7cyuDw%2fsFsSxWcIZV%2fTLUTXDqs3Q%3d%3d > S.no 52
- BPPI, Jan Aushadhi - http://janaushadhi.gov.in/tender/TenderRC098_12032019.pdf
- HP - https://himachal.nic.in/showfile.php?lang=1&dpt_id=19&level=1&lid=18854&sublinkid=18373
- MP - https://mpphscl.in/Home/TenderDetail/?id=2
- Maharashtra - https://arogya.maharashtra.gov.in/Site/Uploads/Tenders/de25f6d5-74da-401d-968a-1174eff08089E%2045%20Inj%20Cefotaxim%20Inject%20Care.PDF