

BLOCK-CHAIN BASED SOLUTION FOR TACKLING COUNTERFEIT DRUGS IN INDIA

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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. 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. Adding to this growing concern, in India, fake medicines is 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.
- With this growing threat of spurious drugs entering the supply chain, especially reaching the hands of customers, there is an imperative need of greater visibility and traceability into the origin of medicines and how they have been handled throughout their journey in the supply chain.

- The blockchain technology—a distributed ledger enabling trusted transactions among multiple parties— helps to permanently register a drug's record in the manufacturer's drug supply chain (serial number, labelling, scanning), leaving no scope for record tampering. At every point of hand/owner change, it records the drug's movement – from manufacturers to logistics, stockists to hospitals, or pharmacies to consumers. In case of a fake drug, the software will detect irregularities. Additionally, critical information such as chemical ingredients of the drug or maintenance of temperature control in case of life saving drugs or vaccines, can also be tracked.
- The use of blockchain based solutions will facilitate the following achievements-
 1. End-to-end traceability of pharmaceutical drugs
 2. Reduced losses related to counterfeiting
 3. Transparency to enhance accountability
 4. Efficient recall management

- **Research Question:**

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

- **Aim:**

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.

- **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.

RESEARCH METHODOLOGY

- **Type of study:** Secondary
- **Study design:** Systematic Literature Review
- **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-**

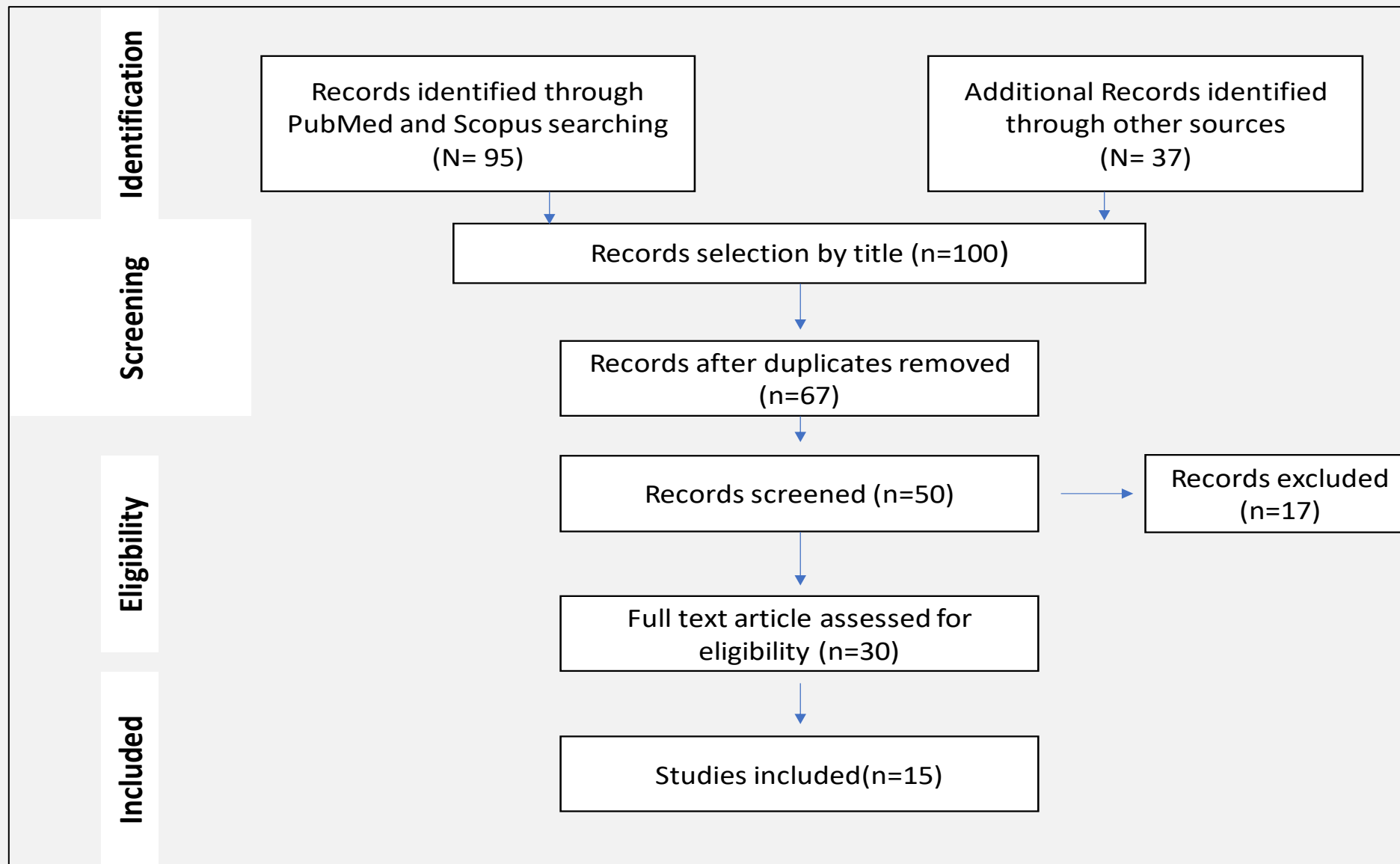
Any information that evaluated or discussed the issue of substandard or counterfeit medicines in India, as well as the introduction of blockchain-based solutions to counter it.

- **Key words searched-**

Blockchain, Healthcare, Counterfeiting, Substandard drugs, Pharmaceutical Supply Chain

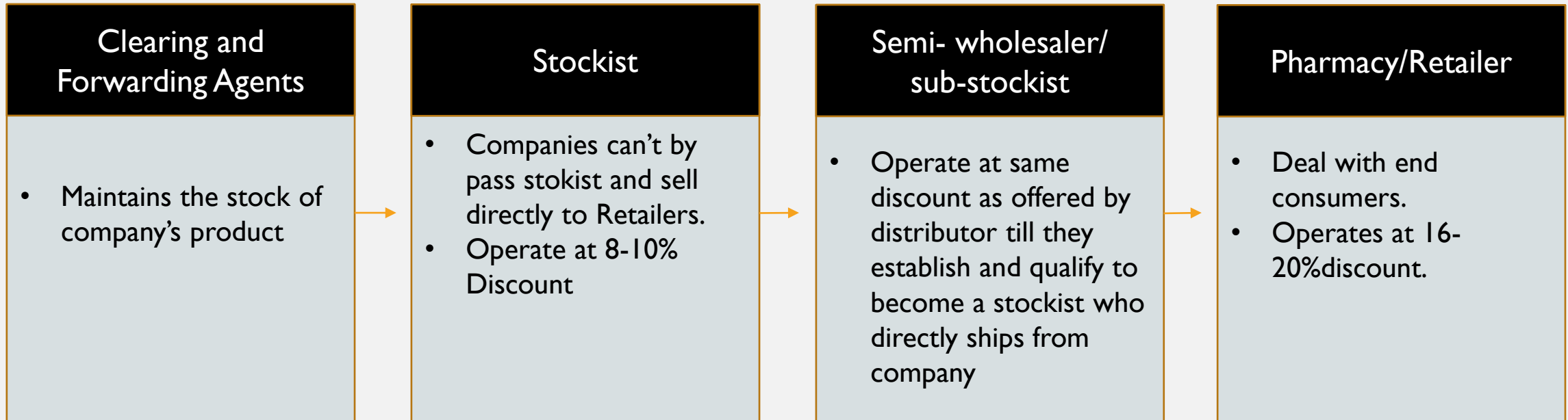
- **Operational Definition-**

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



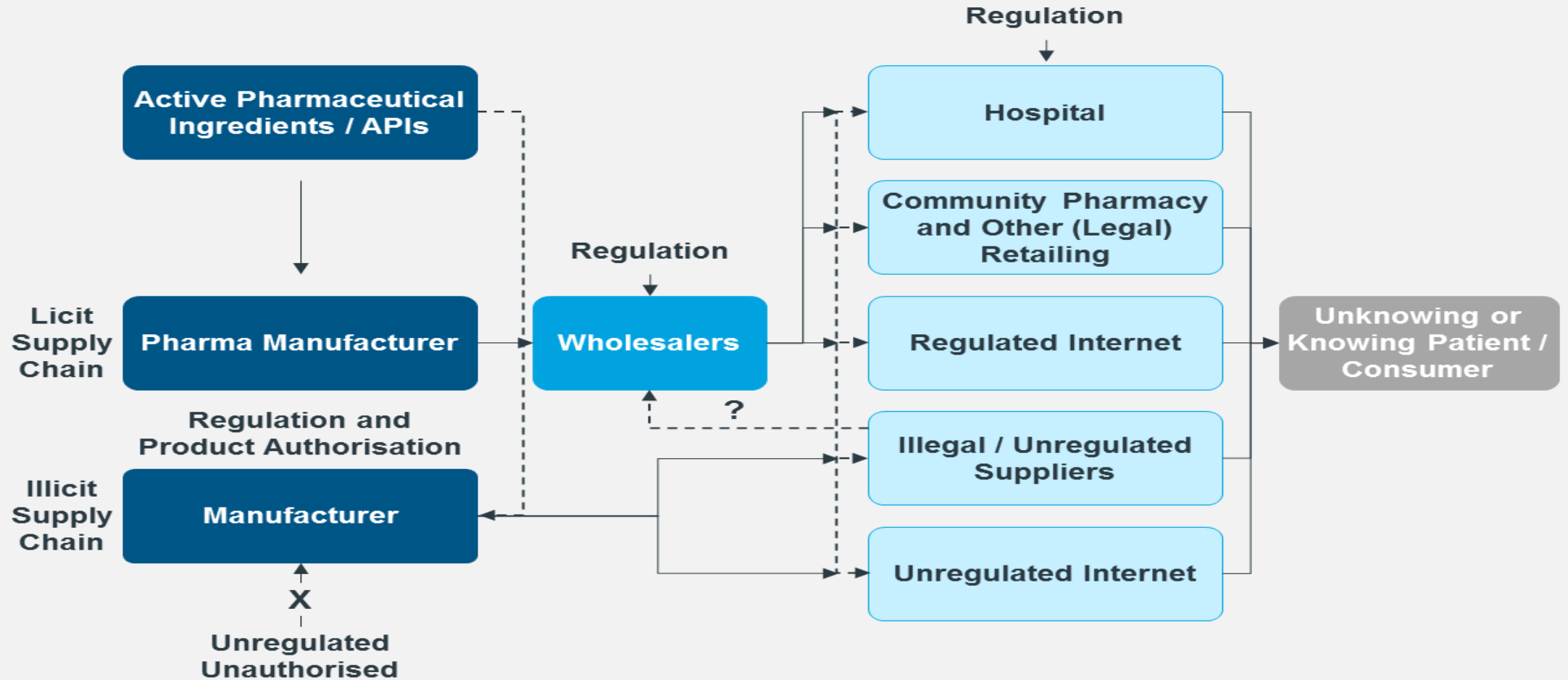
Flow Diagram Depicting the search Process

OVERVIEW OF DRUG SUPPLY CHAIN



Touch points in Indian pharmaceutical Distribution

An illustrative model of the licit and illicit medicine supply chain

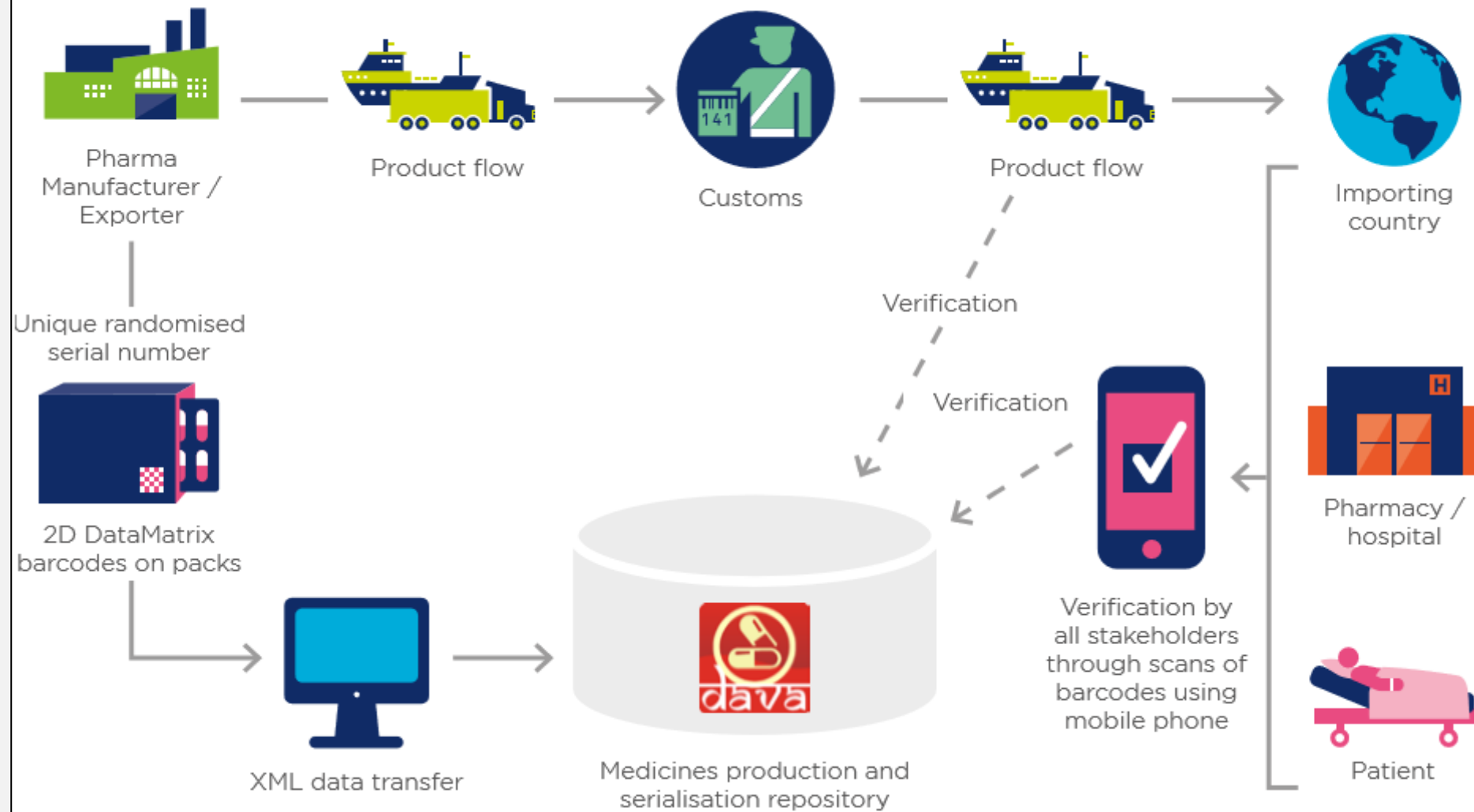


PREVIOUS TRACK AND TRACE INITIATIVES DONE IN INDIA

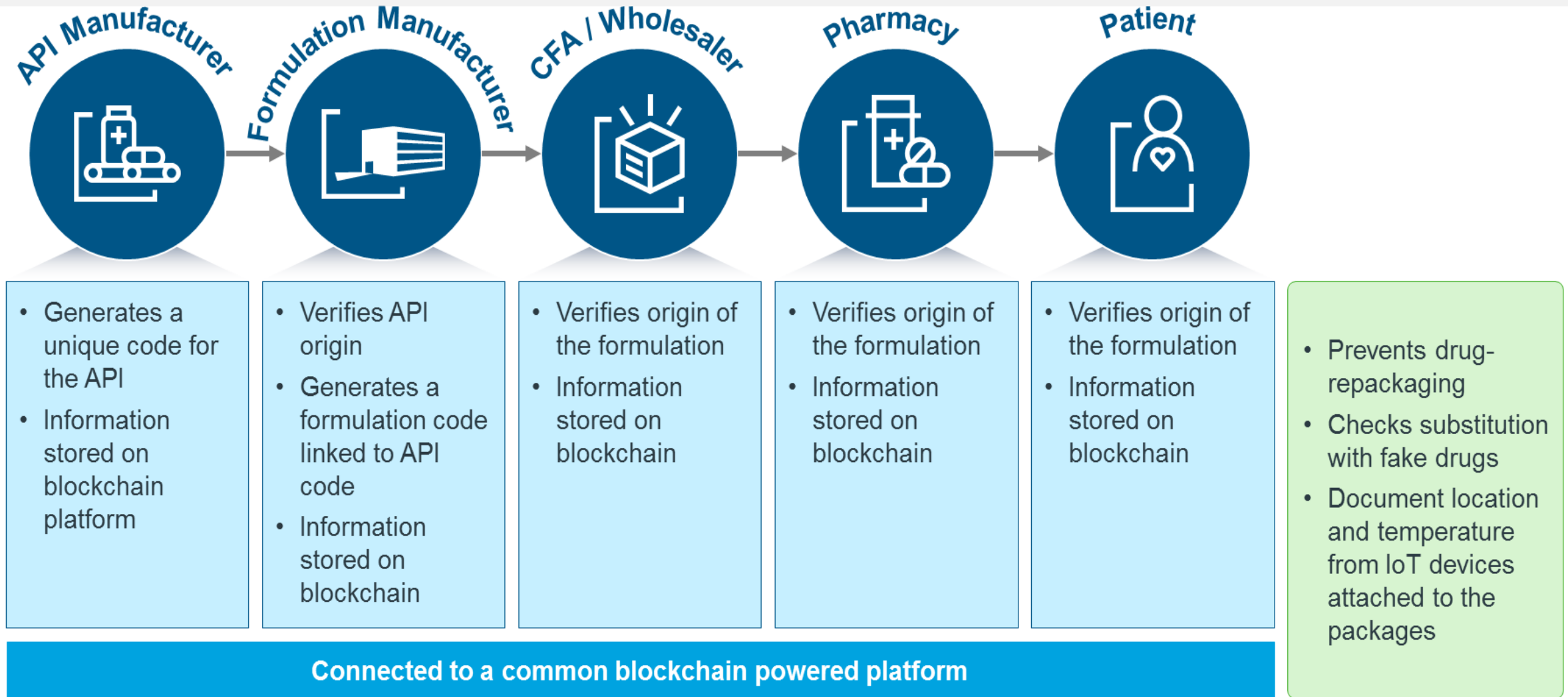
National Informatics Centre designed a new system named Drug Authentication and Verification Application (DAVA), based on the GSI standards, for drug tracking and traceability. The system is based on the use of Global Trade Item Numbers (GTINs) and serial numbers provided by manufacturers for identification 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.

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

How DAVA works



Blockchain Solving the Problem of Fake Medicines



Use of Blockchain Across the Pharma Supply Chain to Enhance Traceability

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
- ❖ Understanding the costs and benefits associated

Single Stakeholder associated costs

- Adding GS1 barcodes to the individual drug strips
- Incorporation of barcode scanners, computers, invoice generations, sensors at each stakeholder level
- Manpower Training at each stakeholder level

Technology associated costs

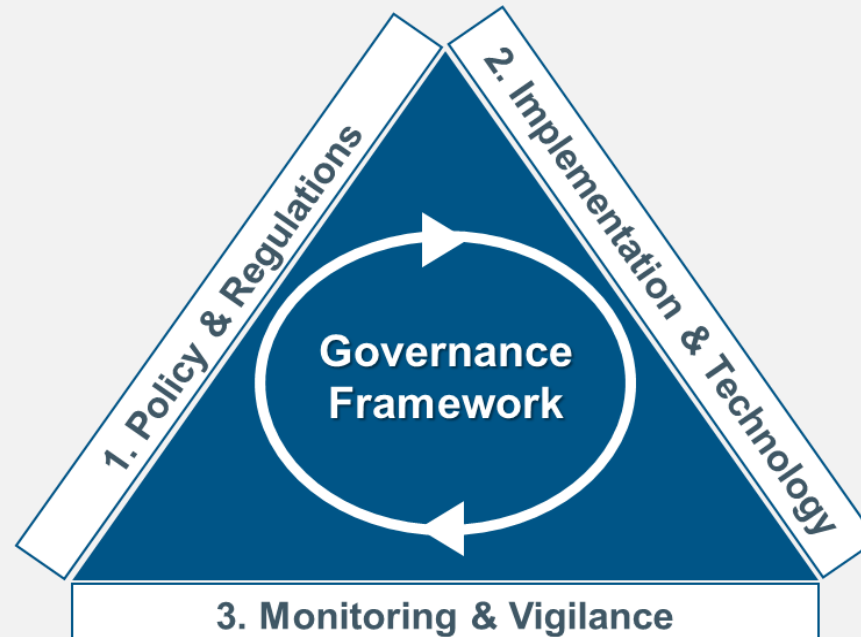
- Technology upgradation at each stakeholder level for '**smart contracts**' *For example, a firm could signal via blockchain that a particular good has been received, or the product could have GPS functionality, which would automatically log a location update that, in turn, triggers a confirmation*
- Incorporation of '**Internet of Things**' to transform the business processes

CONCLUSION:

- While blockchain is still within an innovative phase, it is being actively tested and developed in pilot programs. With success being seen across other industries and regulations requiring greater connectivity and oversight for the pharmaceutical supply, it may not be long until blockchain becomes a fundamental part of the supply 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 advent of blockchain based solutions, the pharmaceutical industry is at the brink of a nation-wide transformation. 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

RECOMMENDATIONS:

- 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.



I. Policy and Regulations

- Develop new and amend existing anti-counterfeiting mechanisms
- 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
- ❖ Provide data protection and information security protocols
- ❖ SOPs and benefits to the value chain stakeholders
- Establish a mandate for unique barcoding
- Conduct cost revisions to facilitate unique barcoding
- Develop and enforce security measures that prevent data leakages/tampering

2. Implementation and Technology Considerations

- Deploy a phase-wise implementation approach
- For Government- Infrastructure should be developed to support adoption of blockchain interventions. This includes the provision of power supply, wireless connectivity
- For Stakeholder- Choosing right sensors and their correct placement, Power Backup and Connectivity

3. Monitoring and Vigilance

- Design effective monitoring & vigilance systems to improve practice and ensure accountability
- Leverage global examples of successful vigilance systems for customization to national context

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THANK YOU!!!!