

Blockchain Technology Factor for Improve Good Distribution Practice in the Pharmaceutical Industry



Erick Fernando, Meyliana, Harco Leslie Hendric Spits Warnars, Edi Abdurachman

Abstract: *The distribution process is one of the processes that occur in all industries, including the pharmaceutical industry. The distribution of medicines in the pharmaceutical industry is the most important to provide quality pharmaceutical products to patients or consumers. With several problems that occur in the distribution of drugs in things that currently should be considered. This happens a lot due to the many drugs that disagree with the provisions or such illegal or false drugs. This research investigates the use of blockchain technology for drug distribution in Indonesia. This research uses a systematic literature review method with related literature. The results of this research found 54 blockchain factors that were used to improve nine aspects of good distribution practices and to ensure the good quality of medicines distributed to consumers.*

Keywords: *Blockchain Technology, Good Distribution Practice, Pharmaceutical Industry*

I. INTRODUCTION

At this time, the World Health Organization classifies that the problem of counterfeit medicines is a problem that occurs in several countries worldwide to provide a consequence of phenomena that represent a significant risk to the life-threatening public. [1], [2]. Another phenomenon that occurs in pharmaceutical companies loses due to the loss of part of the money from the sale of drugs produced so that it suffers losses. [2]. This problem drives the pharmaceutical industry to strengthen the supply chain, which is done by strengthening the drug distribution system that is carried out to consumers. [3], [4].

Distribution is part of the primary driver of profitability in a company, and this is because the distribution has a direct impact on logistics costs and customer experience. [5]. In distribution, several people and entities are generally responsible for the handling, storage, and distribution of these products. [5], [6].

The existing activities in the distribution process are one of the processes that occur in all industries, including the pharmaceutical industry. The distribution process is an important part of the supply chain process that deals with producers and customers. [6]–[8]. In the process of distributing the entities involved and responsible for the elements functioning correctly, guidelines are needed. This guide aims to help ensure the quality and identity of the product during the end-to-end distribution process. Guidelines for good distribution that have been regulated by the government include acquisition, purchase, storage, distribution, transportation, repackaging, re-labeling, documentation, and record-keeping practices [9]. These distribution guidelines, known as good drug distribution methods (GDP), establish appropriate steps to help meet the responsibilities involved in various aspects of the distribution process in the supply chain.

The GDP process is used to overcome the problem of the circulation of counterfeit medicines to maintain the chain of drug safety that describes the need for ways that can be operated in the distribution of pharmaceutical industry drugs to consumers. This GDP system must be built with the support of information technology for supply chain management in order to prevent counterfeiters from replacing medicines in packages with counterfeits or carrying out the circulation process.[2]. Information technology that uses Blockchain technology emerged to address the need for a solution to verify the authenticity of the drugs that circulate in the market [10]–[12].

Blockchain technology is a technology introduced by Satoshi Nakamoto for the first time with his ledger distribution system, consensus, peer to peer, and hashing security system [13]. The changes made to this blockchain technology can provide the performance of an information system for better and reliable [2], [14]–[16]. Blockchain technology provides sophisticated information technology solutions by providing an inter-organizational network that provides distributed, decentralized, and real-time accounting information processes that provide control and traceability in the drug distribution supply chain. [17].

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In this research, it has an agenda in finding blockchain factors that support the drug distribution process in Indonesia in accordance with good drug distribution guidelines (GDP).

II. FOUNDATION THEORY

A. Good Distribution Practice (GDP)

The distribution process carried out in Indonesia has been determined in Regulation of BPOM number HK 03.1.34.11.12.7542 of year 2012 [9], [18]. This regulation has 9 essential aspects among which:

1. Quality management.

The quality system developed must be fully documented and its effectiveness monitored. A change control system must be included in the system that includes the principles of quality risk management.

2. Organization, management, and personnel.

The proper implementation and management of a quality management system and the correct distribution of drug and/or drug ingredients are highly dependent on the personnel who carry them out. There must be sufficient and competent staff to carry out all tasks that are the responsibility of the distribution facility. Management must designate a person in charge of distribution facilities. The person in charge must be a pharmacist who meets the requirements and competencies in accordance with legal regulations. Pharmaceutical workers who have been delegates are required to report their activities to the person in charge.

3. Buildings and equipment.

Buildings and equipment to guarantee the protection and distribution of drugs and/or medicinal materials. Buildings must be designed and adapted to ensure that good storage conditions can be maintained, have adequate security and sufficient capacity to allow good storage and handling of drug, and the storage areas are equipped with adequate lighting to allow all. The activities are carried out accurately and safely.

4. Operational.

All actions taken by the distribution facilities must ensure that the identity of the drug and/or the ingredients of the drug is not lost and that its distribution is handled in accordance with the specifications listed on the packaging. Distribution facilities must use all available devices and methods to ensure that the source of the drug and/or ingredients of drug received comes from the pharmaceutical industry and/or other distribution facilities that are licensed in accordance with the laws and regulations for minimize the risk of counterfeit medicines and/or ingredients by entering the official distribution chain.

5. Self-inspection

Self-inspection should be carried out to monitor the implementation and compliance with GDP compliance and to follow up on the necessary corrective measures.

6. Complaints of drugs and/or drug ingredients that are returned, allegedly false and withdrawn.

All complaints and other information about the potentially damaging drug should be collected, reviewed and investigated in accordance with written procedures. The responsible personnel must approve the drug to be resold in accordance with their authority.

7. Transportation

The transport process must apply appropriate transport methods. The medicine should be transported with storage conditions according to the information on the package. Appropriate methods of transport should be used, including transport by land, sea, air or a combination of the above. Whichever transport is chosen, you must be able to ensure that the drug does not change the conditions during transport that can reduce the quality. A risk-based approach should be used when planning transportation routes.

8. Contractual facilities.

All contract activities must be in writing between the contract grantor and the contract recipient, and each activity must comply with GDP requirements.

9. Documentation.

Good documentation is an important part of the quality management system. Written documentation must be clear to avoid errors in verbal communication and to facilitate follow-up, including batch history, instructions, and procedures.

B. Blockchain

Blockchain is a new technology that was originally introduced by a person or group of people called Satoshi Nakamoto in 2008. At the beginning of the emergence of the blockchain used in the cryptocurrency transaction process which was originally known as bitcoin [13]. Blockchain uses peer-to-peer networks, time stamp transactions with hashing, in chains with Markle trees using hash-based proof-of-work that takes place in consensus, and is recorded using a distributed ledger to form records that cannot be changed [12], [13].

III. METHODOLOGY

This study uses a systematic review of the literature review to study the blockchain factors associated with a good distribution of drug (GDP). This study uses keywords that are relevant to the topic sought: pharmaceutical blockchain technology, blockchain, and drug distribution and implement it if the blockchain is in the drug distribution. The SLR process is carried out with the obtained process seen in Figure 1:

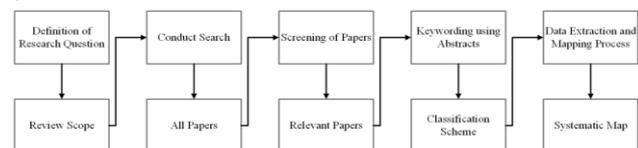


Figure 1. System mapping process

1. Definition of the research question

In the first stage of this investigation, the mapping of relevant research questions. This mapping aims to provide an address from a study of blockchain technology on drug distribution in the pharmaceutical industry. So, in this study, the main question can be identified in the blockchain technology factors that can be applied at each stage of the drug distribution process and explore why these factors can help the drug distribution process.



2. Conduct search

In the second stage, this research is the stage where all relevant articles are searched. The search method uses the Boolean logical approach with AND and OR. The keywords used in this study include Blockchain technology and distribution pharmacy, Blockchain technology and good distribution practices, Blockchain technology or drug distribution, Blockchain technology and drug distribution. Articles were searched using the most up-to-date article database, including Emerald, Taylor and Francis, IEEE Explore and Science Direct, MDPI. This approach is carried out so that there are no biases in the search for relevant articles.

3. Review of all documents

At this stage, search for related research articles that have been searched according to the search keywords. From the search process, there are still many unrelated articles in the research questions. At this stage, there are several stages, among others: The first stage of detection carried out according to the title of the article found in accordance with this investigation. The second stage of selection is carried out in a more abstract reading of each article that has passed the previous phase and uses specific inclusion and exclusion criteria to filter each article. This process will obtain a study of the research that has been directed and relevant depending on the content of the article.

4. Summary keyword base

At this stage, find documents that are appropriate through the summary along with the keywords. According to Petersen et

al., this process goes through two steps. In the first step, read the keywords and abstract concepts contained in the article to identify the contribution of the article. The second step is to read and better understand the article. Then read the document selected as a whole. This results in a systematic map of grouped categories formed from all relevant documents on the research topic.

5. Data extraction and mapping process

At this stage, the data of the references obtained are extracted so that the information necessary to answer this research question can be designed. The data collected may be in the form. Job title, author's name, author's country, and type/place of publication. The remaining data items are collected after reading the article. This data element includes, e.g. study the objectives and main conclusions of each work. We collect data elements that are extracted in Excel, which helps us organize and analyze data so that they can be assigned according to the purpose.

IV. ANALYSIS AND DISCUSSION

The distribution process carried out in Indonesia has been determined in the National Agency of Drug and Food Control (BPOM) regulations. This regulation has nine aspects that are in the GDP. In the distribution process, many aspects that affect according to table 1 will be assigned to a blockchain factor that can be developed and provide a better influence for the distribution process of this medicine based on the reference that can then be seen in table 1.

Table 1. Blockchain factor mapping in aspects of good distribution practice

No	Variable	Sub Variable	Factor Blockchain	Improve with blockchain	Ref
1	Management Quality	Quality planning	Efficiency	The efficiency of the processes carried out in the quality planning of drug distribution	[19]
		Quality improvement	Quality	Improvement of drug quality can be fulfilled	[20]
		Quality System	Evaluation	Evaluation in ensuring the whole process of developing and supplying pharmaceutical drugs	[21]
		Quality control	Real-Time	Process quality and real-time product monitoring	[3]
			Reliability	A more reliable monitoring and quality control system	[3]
Quality Assurance	Monitoring	Monitoring ability to ensure the entire process of developing and supplying pharmaceutical drugs	[21]		
2	Organization and Management	Ability	The ability of an organization to meet or exceed stakeholder expectations in terms of meeting the resources, production, and delivery of products	[22]	
		Cost-Effective	The organization carries out cost savings on drug supply chains	[23]	
	Person in charge	Privacy Protection	The system must protect the privacy of users and organizations with appropriate mechanisms	[24]	
	Personnel	Authorization	Authority in the supervision of a process	[25]	
	Training	Sharing information	Sharing drug information for the learning process of related stakeholders	[26]	
	Hygienic	Hygienic	Hygienic in the process of making and distributing drugs	[3]	

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No	Variable	Sub Variable	Factor Blockchain	Improve with blockchain	Ref
3	Building and Equipment	Building	Access Traceability	Access tracking in buildings can be done easily	[21]
		Temperature & Environmental Control	Temperature Controlling	Temperature control in storage	[27]
		Equipment	Open-source access	Provides open access to all who are entitled to use the device in the drug distribution process	[21]
		Computer system	Ease of use	An easy-to-use tracking system so that it can monitor the movement of drugs well	[28]
		Qualification & Validation	Suitability	The suitability of buildings and equipment used with the products produced (e.g. storage locations for liquid drugs, solid drugs, gassy medicines, etc.)	[29]
4	Operational	Supplier Qualifications	Authentic supplier	The authenticity of suppliers who meet the standards to ensure the distribution process	[27]
		Customer Qualifications	People Trust	Trust with actors (producers, retailers, and customers) who are certified and registered in the system	[30]
		Drug Receipt	Confirmation	Confirmation of receipt of drugs sent to improve the integrity	[19]
		Drug Storage	Accuracy	Accuracy in determining the storage of drugs in place	[11]
		Drug Separation	Accuracy Identification	Accurately identify the determination of the place of pharmaceutical products	[11]
		Drug Annihilation	Extermination Traceability	Tracking of drugs that were destroyed	[28]
		Taking drug	Authenticity	Pharmaceutical distributors verify the authenticity of the product in the process of taking drugs	[22]
		Packaging drug	Serialization	Product serialization for authentication and traceability	[27]
		Drug Delivery	Tracking	Track drug distribution in drug supply chains	[31]
			Traceability	A good traceability system for the authenticity of drugs in the process of drug delivery from the production chain, logistics, certification, and drug sales	[32]
Export dan import	Delivery Trust	Trust in the drug delivery process	[33]		
5	Self-Inspection	Independent	Independent	Freedom from external interventions in drug distribution systems	[21]
		Audit	Audit trail visibility	Generate audit trails available in a format that can be read and tracked	[34]
		Documentation	Document provenance	Provide an initial document that was recorded to facilitate the audit process	[28]
6	Complaints about the drug or drug ingredient are suspected to be false and the withdrawal process	Drug complaints	Real-time drug complaint	Real-time monitoring of drug order complaints	[27]
			Transparency	Transparency of drug complaints from claims of drug distribution processes	[27]
		Return drug	Verification drug return	Verifying returned drugs	[35]
		Drugs suspected to be fake	Drug Allegedly	Identification of drugs that are suspected to be false to improve the safety and security of drug supply chains	[31]
		Withdrawal / Recall	Tracing recall process	Tracking the drug withdrawal process	[27]
7	Distribution Facilities Based on Contract	Contract Giver/recipient	Digital identity	Digital identity Contract giver/recipient in the supply chain	[3]
		Contract scope	Security contract	Security of contracts in checking contracts conducted at distribution facilities	[3]
			Medicinal properties	The contract is used to detect products that cannot meet drug efficacy standards	[3]
			Drug Quality	Contracts are used to monitor drug quality	[3]

No	Variable	Sub Variable	Factor Blockchain	Improve with blockchain	Ref
8	Documentation	Documentation Form	Digitalize documents	The digitized documents are used and distributed together.	[36]
		Storage	Decentralized	A decentralized database system for storing documentation data	[21]
		Information quality	Relevant	Interested parties can access information that is appropriate for making decisions	[37]
			Timeliness	Information shared among supply chain partners is received in a timely manner.	[38]
			Accuracy	Accurate information is shared among supply chain partners	[38]
			Comprehensiveness	Completeness and accessibility of data to support operational processes and decision making	[38]
			Usefulness	Information used for use by stakeholders in the drug distribution process (e.g., drug production information)	[37]
9	Transportation	Transportation & Products in Transit	Traceability vehicle data	Vehicle data traceability, road safety, and driver data help the distribution process	[38]–[40]
			Traceability schedule delivery	Tracking schedules to reduce potential disruptions to the distribution process. (e.g., delivery schedule)	[38]
		Drug in Delivery	Identity product	All stakeholders in the supply chain can access the identity of the drug being distributed	[38]
		Container, Packaging, and Labeling	Data Container, Packaging and Labeling	Data or container information is available so that they can be monitored and accessed by the parties involved	[22]
		Drug Transportation Special Conditions	Monitoring data of special conditions drug	Monitoring data of drugs that have special conditions during transportation (e.g., Temperature and humidity)	[22]
		Vehicles & Equipment	Vehicle & equipment data	Digital identity data related to vehicles and equipment can be tracked and secured during transportation	[22]
		Temperature Control During Transportation	Controlling data temperature	The quality of temperature control data can be verified by the parties concerned	[41]

This study provides an overview of the blockchain factor that can better improve the entire drug distribution process. The blockchain factor found 54 factors. Of each factor, blockchain technology has been assigned to each secondary aspect of each aspect of GDP, so it clearly improves:

1. Management Quality aspects improve when determining the quality of a drug that will then be distributed from the pharmaceutical industry to consumers.
2. The organizational management and personnel aspects that improve the organization and the pope who directs the distribution process will be good, hygienic, and profitable.
3. The building and equipment receive improvements Tracking access in buildings can be done easily, Control storage temperature, Provide open access to all who have the right to use the device in the drug distribution process, System Tracking that is easy to use so you can monitor the movements of drug correctly, Compliance buildings and equipment used with the product produced (for example, storage locations for liquid drug, solid drug, gas drug, etc.)
4. Improvement of operational aspects Authenticity of the supplier that meets the standards to guarantee the distribution process to obtain producers, retailers, and customers that are certified and registered in the system. Confirmation of the receipt of drugs sent to improve integrity, Accuracy In determining the storage of medicines in the place, precise

identification of the location of pharmaceutical products that facilitate a good traceability system for the authenticity of medicines in the process of sending medicines from the production chain, logistics, certification and sale of medicines to rely on the process of sending medicines of each of the interested parties.

5. The aspects of self-inspection are improved from the free side of external interventions in the drug distribution system, providing an audit trail available in a format that can be read and tracked and supported by the initial document registered to facilitate the audit process.
6. It is suspected that complaints about the drug or drug ingredient are false and the appearance of the withdrawal process is improved in real-time monitoring, transparency, and identification of drug claims, which are returned to improve the security of the drug supply chain.
7. Distribution facilities based on the contract receive an aspect improved digital identity for each giver/recipient of the contract in the supply chain, the security of the contract when examining the contracts made in the distribution facilities and the contracts used to control the quality of the drug.

8. Documentation aspects receive improvement documents that have been digitized so that they can be distributed and stored in a decentralized database system so that interested parties can access the appropriate information for decision-making. Information shared between supply chain partners is received on time. Accurate information is shared between partners in the supply chain, integrity and accessibility of data to support operational processes and decision making, information used for interested parties to use in the drug distribution process (for example, drug production information).

9. The transport aspect improves traceability with digital identity data related to vehicles and equipment so that you can access vehicle data, road safety, and driver data to help the distribution process so that it can be tracked and secured. during transport, schedules can then be tracked to reduce the possibility of interference with distribution process (e.g. delivery schedule) and can access, monitor the identity of the medicines distributed through the data or information of the available container, monitor data on drug that have special conditions during transport (for example, temperature and humidity).

V. CONCLUSION

This study provides an overview of the blockchain factor that can better improve the entire drug distribution process. The blockchain factor found 54 factors can be improved each aspect di GDP. Of each factor, blockchain technology has been assigned to each sub-aspect of each aspect of GDP, so that the drug distribution process is well implemented and properly and properly controlled from the pharmaceutical industry to the consumer. The industry provides quality assurance of the drug

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