Journal of Contemporary Issues in Business and Government Vol. 28, No. 03, 2022
https://cibg.org.au/

P-ISSN: 2204-1990; E-ISSN: 1323-6903
DOI: 10.47750/cibg.2022.28.03.071

Factors influencing adoption of blockchain technology in the pharmaceutical supply chain for prevention of counterfeit drugs: Environmental Perspective

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ABSTRACT

In regard to the pharmaceutical supply chain, the estimate of counterfeit medicines account for 10 to 15 percent. In underdeveloped nations, counterfeit pharmaceuticals account for 30 percent of total drug sales. According to the World Health Organization (WHO) [1], Counterfeiting has become one of the world's largest and fastest growing illegal businesses and, due to increased production and distribution of counterfeit goods and their ability to be produced in large quantities in a short amount of time, annually it is projected to be worth about 600 billion USD according to the International Anti-Counterfeiting Coalition [3]. The high incidence of counterfeit medications entering the global supply chain has long been a source of concern for the pharmaceutical industry. Counterfeit medications are those that are manufactured or labelled falsely to give the impression of being real, according to the WHO [1]. Because they may contain variable quantities of the active pharmaceutical component or are made in uncontrolled and hazardous circumstances, these counterfeit medications can be harmful, if not fatal, to patients' health [4]. In addition to the negative impact on patients, counterfeit drugs have a direct impact on pharmaceutical businesses' profits and reputations, since they cannibalise real product markets and tarnish brand image and trustworthiness [5]. To protect human health globally, the WHO, with the help of the IMPACT Group, the European Union, and the G8 combined, is determined to accomplish the aim of combating crime with the help of a digital approach such as blockchain technology. The current paper evaluates the sub factors like regulatory/government support, Industry standard, Policies & Law in terms of international regulation, Mutual trust between the stakeholder on the adoption of BCT technology in pharmaceutical supply chain for counterfeit prevention.

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Keywords: Blockchain Technology, Counterfeit Drugs, Pharmaceutical Supply Chain

INTRODUCTION

From drug discovery through medication development and regulatory approval, pharmaceutical research and development is a lengthy process that can take several years [7]. When all of the development steps have been completed and a standard drug has been created, the next challenge for manufacturers is to deliver the product to the visibility and control for manufacturers and regulatory intended patient in its original form, ensuring that the patient receives a genuine product created by a legitimate manufacturer rather than a counterfeiter.

For decades, the pharmaceutical industry has been plagued by the reality of counterfeit medications entering its intricate supply networks. Companies are seeking creative ways to address the growing danger to patient lives and brand reputations. The emergence of digitisation, particularly blockchain technology (BCT), has given birth to new optimism for resolving the pharmaceutical industry's worldwide supply chain problem.

However, the pharmaceutical industry's existing Supply Chain Management (SCM) systems are obsolete or outdated, failing to offer authorities over medication delivery and distribution [8]. As a result of this SCM situation, counterfeit medicines are produced, distributed, and consumed. These fake medicines have a negative impact on the health of the human body both directly and indirectly, which is considered a severe public health threat and a growing global concern [9]. Regulatory bodies have key role in creating a framework which would help in adoption of blockchain technology in pharmaceutical supply chain.

LITERATURE REVIEW

It is crucial to define the term digitisation, which originates from the English word digitalisation and may also be translated as digitization. Presently, based on the requirements of practical transcription, the terms digitisation or digitization have become widespread. This is a European and American research tradition that shows the effects of the transition from analogue to digital types of information encoding, which transfers any kind of information into digital form [10]. The social implications of digitising the economy include increased access to financial services and improved health care quality through the digitisation of patient data. One possible solution is to take advantage of the development of digitisation to improve the traceability of all goods and their constituent parts throughout the global supply chain. Genentech has taken the first step by investing in the Medi-Ledger Project in collaboration with other major pharmaceutical firms [6]. During that process, the initiative is to consolidate all stakeholders in the supply chain's medicine delivery records into a single digital system. Consequently, each stage of the distribution process will be digitally recorded, producing a permanent record of when the medication is traded between parties. As a result, in addition to making it more difficult for criminals to introduce counterfeit materials or steal medications from the supply chain, it enables faster identification and investigation of disruptions [11].

First and foremost, it is important to provide the necessary support for a successful worldwide battle against counterfeit drugs. This necessitates the deployment of cutting-edge digital technologies such as BCT to prevent counterfeit drugs. Establishment of a uniform electronic system is required for the identification of

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products, including medications, in each nation, which would be publicly accessible on the internet, including to every prescription drug user. The worldwide, multinational scale of the drug identification challenge is a key factor [12]. The World Health Organization (WHO), which is currently managing these issues, should serve as the global engine of digitisation to counter pharmaceutical counterfeiting. BCT has been identified as key technology for the pharmaceutical supply chain security and prevention of counterfeit drugs. It is important to create an international programme coordinated by the WHO to combat medication counterfeiting on a worldwide scale.

The creation and execution of this programme should include participation from authoritative international organisations such as the European Union, the Eurasian Economic Union and other international bodies. Such effort should be made at the national level by relevant health ministries, either via the development of suitable subordinate institutions or through collaboration with national digitisation agencies to identify such activities and resolve them accordingly [13].

In 2011, the EU parliament and the council presented Directive 2011/62/EU and commenced a cohesive staggered battle against their entrance within the legitimate supply chains of the EU Union (EU) Member States. It altered the key drug directive 2001/83/EC, which is referred to as the Falsified Medicine Directive (FMD).

The principal objective was to set out a comprehensive legitimate system that connects all partners within the drugs sector [14]. In the following years, the EU specialists embraced the strengthening of legislation and rules to also manage suitable and convenient execution of the new measures. Assigned Regulation (EU) 2016/161 is a highly important demonstration that enforced the formation of a focused European track-and-follow framework with visible serialisation and checks for medications prescribed by doctors. In a different method to that used by other nations, the EU chose the book-end approach, which releases wholesalers from mandatory confirmation except in specific cases with expanded risk of adulteration [15].

BCT upholds straightforwardness, security and adaptiveness in information sharing among completely different businesses in several stockpile chains [16]. In BCT, the conveyance of information promotes trust in the quality and accuracy of that information while not requiring consulted specialists to oversee unified information sets [17].

Although Xu [18] did not specify BCT by name, the difficulties demonstrated show that BCT may well be a promising innovation for simpler SCM, whether or not others, including Garg [16], have detected completely different obstacles that continue to hinder the execution of BCT. To aid this, Idrees [19] has distinguished supply chain processes in which BCT may hypothetically be used, for example, in characterising data models, handling agreements and maintaining electronic records. Since the continuation of creating future supply chains intensifies as they expand and add businesses, international supply chains face particular strain from further elaboration of various legal conditions, longer vehicle distances and different business societies. Such patterns will limit access to high quality data that empowers partners in the supply chain to form additional educated, proactive selections that work on the expansion of their supply chain, as literature related to SCM has solidly outlined. All things considered, supply chains today, especially large ones, frequently seek the transparency and ease that empowers businesses therein to decide

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on selections of slender data, for the foremost half hurts supply chain proficiency. Such obstacles may well be survived, in any case, by employing BCT and its capability to support straightforwardness, discernibly and security. Simultaneously, the benefits of BCT accompany value.

As is often the case with emerging innovation, the degree of the value given by the blockchain-driven joint effort framework is being scrutinised by different researchers from an associated assortment of fields, from the tasks and information the framework executes to framework and digital planning. BCT empowers trust

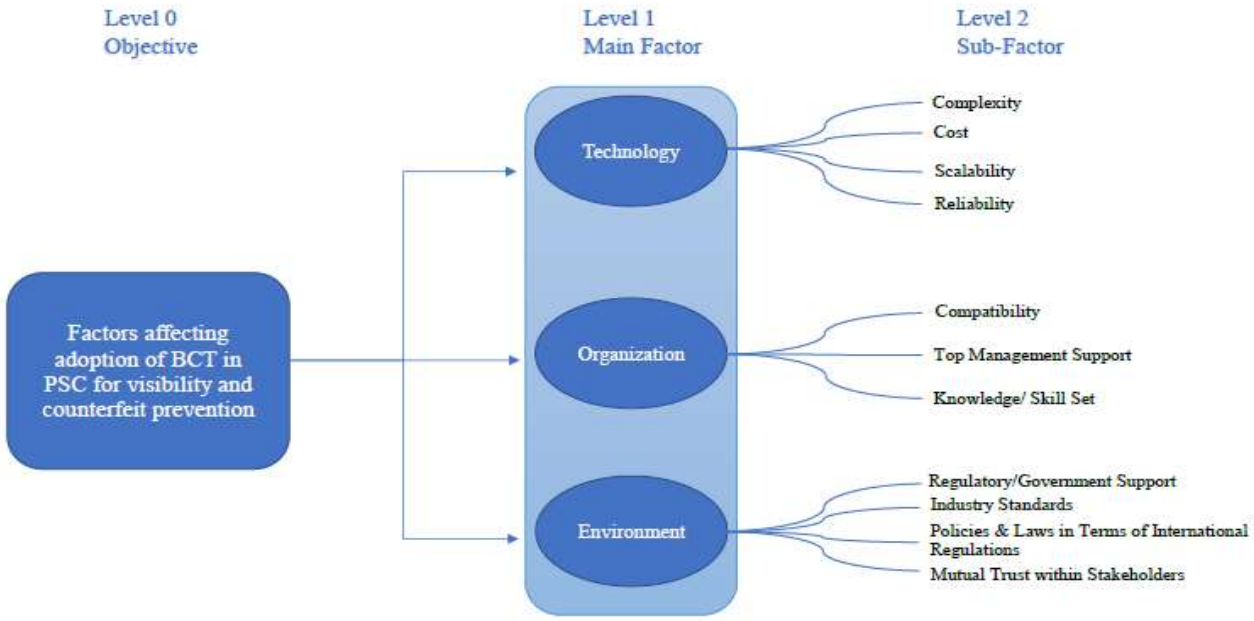

Figure 1: Research Framework 1

less organisations because it permits companies to operate while not trusting in each other. Through rigorously marked records, blockchains will approve the reliability of individuals to affirm WHO activities, and when and where they are taking place. This arising innovation offers a reason for conditional data sharing across networks while not requiring confidence in the trustworthiness of cooperating executives. BCT has huge potential, as it can help achieve the goal of pharmaceutical supply chain security and visibility. Thus, a further literature review was performed to identify the key factors that impact the adoption of BCT in pharmaceutical supply chains for the prevention of counterfeit drugs.

Provide broad definitions and discussions of the topic and incorporate views of others (literature review) into the discussion to support, refute, or demonstrate your position on the topic.[1]

Research Problems and Research Questions

The existing research examining and understanding the environment factors impacting the adoption of BCT in pharmaceutical supply chains for the prevention of counterfeit drugs is extremely limited. Some articles have reported the adoption of BCT in pharmaceutical supply chains; however, they do not provide any

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insights on environmental factors impacting the adoption of BCT. In this context, currently there have been no studies reported that have examined the environmental factors impacting adoption of BCT from the perspective of operations managers managing risks in supply chain processes either in developed or developing economies [20]. Based on the potential usefulness of BCT technology in pharmaceutical supply chains, the following research questions are raised:

(i) Do any or all the stated environmental factors (i.e., regulatory/government support, Industry standard, Policies & Law in terms of international regulation, Mutual trust between the stakeholder) impact or influence the adoption of BCT in the pharmaceutical supply chain for prevention of counterfeit drugs?

Research Objectives (Brief Solutions to Research Problems)

The objective of this research is to bridge this knowledge gap in the supply chain literature concerning the factors impacting the adoption of BCT for risk management in pharmaceutical supply chains. This leads to the following research objectives motivating our current research:

(i) To identify stated environmental factors (i.e., regulatory/government support, Industry standard, Policies & Law in terms of international regulation, Mutual trust between the stakeholder) have impact and influence on the adoption of BCT in pharmaceutical supply chains for the prevention of counterfeit drugs.

The detailed mapping of the research gaps and findings was conducted at this stage. The research framework was developed based on the gaps and findings. The research framework is presented in Figure 1.

Methodology

This research investigates the factors that are critical for the adoption of BCT in pharmaceutical supply chains for prevention of counterfeit drugs. The first stage of the study involved a detailed critical literature review of 200 research articles from secondary sources published in leading international journals and publications. This stage has helped to identify the key research gaps up to and including the year 2022.

The second stage of the study included developing a questionnaire, incorporating all variables as established by the critical literature review. The next stage included circulating the questionnaire to relevant participants for pilot studies.

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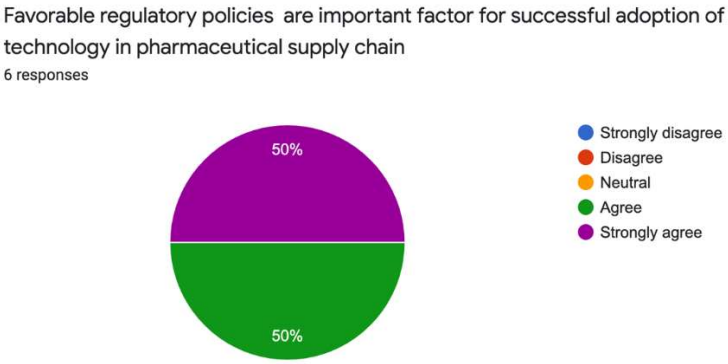
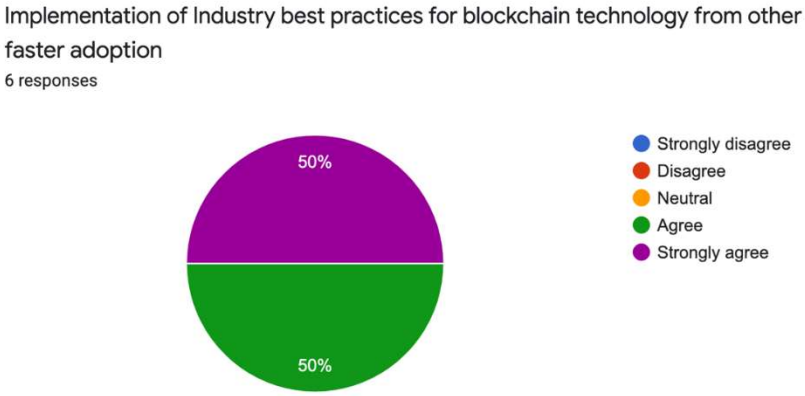
QUESTIONNAIRE DETAILS:

ENVIRONMENT (EN)

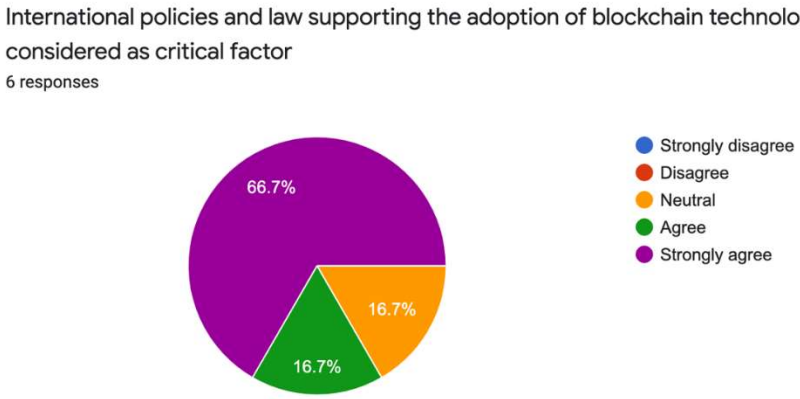
EN1 : REGULATORY / GOVERNMENT SUPPORT



EN2 : INDUSTRY BEST PRACTICES



EN3 : POLICIES/LAWS INTERMS OF INTERNATIONAL REGULATIONS



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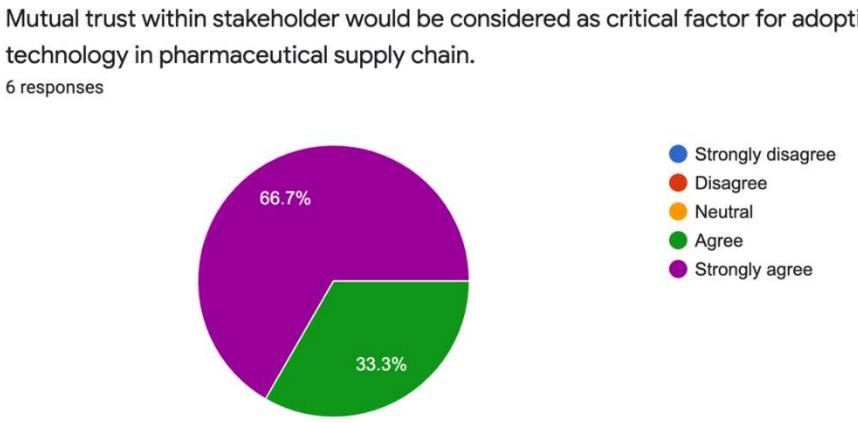
EN4 : MUTUAL TRUST WITHIN STAKEHOLDERS



CONCLUSION

The factors identified from the literature review for the environment (i.e., regulatory/government support, Industry standard, Policies & Law in terms of international regulation, Mutual trust between the stakeholder) has impact on the adoption rate of BCT in the pharmaceutical supply chain. The study would further validate the positive and negative correlation with the adoption rate of BCT in pharmaceutical supply chain. The results from the study would be presented in next paper.

. **ACKNOWLEDGMENT**

Nil

Conflict of Interest

The authors of this publication declare there is no conflict of interest**.**

Funding Agency

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

REFERENCES

[1] World Health Organization, "Substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products," World Health Organization, 2-5, 2016.

[2] H. Julian, S. Philip, and M. Julian, "Combating the spread of fake drugs in poor countries" in International Policy Conference on e-Health Networking, Applications and Services, Healthcom, 2016.

[3] E. Roxann, D. Lisa, and P. George, "Anticounterfeiting in the fashion and luxury sectors: Trends and strategies" in Anti-Counterfeiting—A Global Guide, 2013.

[4] Pharmaceutical Security Institute (PSI). Counterfeit situation, 2017.

P-ISSN: 2204-1990; E-ISSN: 1323-6903
DOI: 10.47750/cibg.2022.28.03.071

[5] E.A. Blackstone, J.P. Fuhr Jr, and S. Pociask, "The health and economic effects of counterfeit drugs" in American Health & Drug Benefits, 7(4), 216, 2014.

[6] L. Nørfeldt, J. Bøtker, M. Edinger, N. Genina, and J. Rantanen, "Cryptopharmaceuticals: increasing the safety of medication by a blockchain of pharmaceutical products" in Journal of Pharmaceutical Sciences, 108(9), 2838-2841, 2019.

[7] M. Dadkhah, M. Mehraeen, F. Rahimnia, and K. Kimiafar, "Users' Perception of Medical Blockchain" in Advanced Pharmaceutical Bulletin, 11(2), 206, 2021.

[8] M. Arumugam, S. Deepa, G.R. Sreekanth, G. Arun, and S. Nilesh, "Counterfeit drugs prevention using block chain techniques" in IOP Conference Series: Materials Science and Engineering (Vol. 1055, No. 1, p. 012109). IOP Publishing, February 2021.

[9] V.V. Ilkov, T.V. Lysenko, S.P. Myrnyi, S.S. Tuchkov, and I.O. Shekhovtsova, "Protection of a human, human rights and international practices in counterfeiting medicines: management and administration issues in the globalized environment" in Journal of Complementary Medicine Research, 11(2), 98-104, 2020.

[10] A. Berke, "How safe are blockchains? It depends" in Harvard Business Review. [Online]. Available: https://hbr. org/2017/03/how-safe-are-blockchains-it-depends [accessed Aug. 30, 2018].

[11] V. Pashkov, A. Soloviov, and A. Oler, "Legal aspects of counteracting the trafficking of falsified medicines in the European Union aspekty prawne przeciwdziałania obrotowi podrobio nymi lekami w unii europejskiej," Wiad Lek, 71(4), 843-849, 2017.

[12] F.Y. Vladimirovich, D.P. Grigorovich, D. Yermolenko, K. Hanna, and V.V. Ilkov, "Protection of human rights in the context of combating of counterfeiting medicines: theoretical and legal issues of international cooperations" in Indian Journal of Forensic Medicine & Toxicology, 14(4), 2020.

[13] K. Shamsi, K.E. Khorasani, M.J. Shayegan, "A secure and efficient approach for issuing KYC token as COVID-19 health certificate based on stellar blockchain network" in arXiv, 2020. published online Oct. 5. [Online]. Available: https://dx.doi.org/10.22133/ijwr.2020.250275.1070 (preprint).

[14] A. Celesti, A. Ruggeri, M. Fazio, A. Galletta, M. Villari, and A. Romano, "Blockchain-based healthcare workflow for tele-medical laboratory in federated hospital IoT clouds," in Sensors (Basel); 20: 2590, 2020.

[15] H. Xu, L. Zhang, O. Onireti, Y. Fang, W.B. Buchanan, and M.A. Imran, "BeepTrace: blockchain-enabled privacy-preserving contact tracing for COVID-19 pandemic and beyond," in arXiv; published online May 20, 2020. https://doi.org/10.1109/JIOT.2020.3025953 (preprint).

P-ISSN: 2204-1990; E-ISSN: 1323-6903
DOI: 10.47750/cibg.2022.28.03.071

[16] K. Hasan, S. Mahmood, M.C. Carras, and A. Labrique, "Global preparedness against COVID-19: we must leverage the power of digital health," JMIR Public Health Surveillance; 6: e18980, 2020.

[17] C. Garg, A. Bansal, and R.P. Padappayil, "Optimizing the implementation of COVID-19 'immunity certificates' using blockchain," in J Med Syst; 44: 140, 2020.

[18] S.M. Idrees, M. Nowostawski, and R. Jameel, "Blockchain-based digital contact tracing apps for COVID-19 pandemic management: issues, challenges, solutions, and future directions," JMIR Med Inform; 9: e25245, 2021.

[19] Z. Qiu and Y. Zhu, "A novel structure of blockchain applied in vaccine quality control: double-chain structured blockchain system for vaccine anticounterfeiting and traceability," in J Healthc Eng; 2021: 6660102, 202