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Smart-Contract Based Framework for Online Pharmacy Product Anti-counterfeiting

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Abstract: The role of online pharmacies in supplying pharmaceutical products has witnessed substantial growth. However, it is crucial to highlight that online platforms and supply chain infiltration constitute a significant portion of counterfeit pharmaceutical products, accounting for 40.9% of counterfeit product distribution; owing to their inherent characteristics, online pharmacies possess the capability to procure products from a diverse array of suppliers. The records utilized for consumers to verify product authenticity are centralized, rendering them susceptible to manipulation, including the potential inclusion of products from unregulated supply chains. The proposed framework capitalizes on the immutability of blockchain data to secure the integrity of authentication records and smart contracts to facilitate interaction with blockchain records. The study employed sequence diagrams to conceptualize the framework's design and utilized algorithms for its practical implementation. By incorporating smart-contracts and implementation of hashing for backend data records, consumers can place trust in the integrity of these records, which plays a pivotal role in authenticating pharmaceutical products distributed by online pharmacies.

Keywords: Smart-Contract; Blockchain; Hashing; Algorithm; Pharmaceutical; Anti-Counterfeiting

1. INTRODUCTION

Information Communication Technologies (ICT) proliferation has ushered in diverse avenues for customer engagement, including business-to-customer (B2C), particularly prevalent in the pharmaceutical sector (Li et al., 2019). B2C pertains to online pharmacies, where all interactions between pharmacists and customers transpire in the virtual domain, within this framework, consumers electronically transmit their prescriptions to an online pharmacy, dispensing the prescribed pharmaceutical products through digital channels (ISACA, 2020). In their 2019 research, Garge et al. underscored many favorable attributes linked to pharmaceutical products distributed via online pharmacies. These included heightened accessibility, enhanced convenience, competitive pricing relative to brick-and-mortar counterparts, and an augmented level of consumer privacy. Nevertheless, their study emphasized the imperative for continued investigation to address potential hazards associated with online pharmacies, such as the circulation of counterfeit pharmaceutical products and improper utilization of medications (Chordiya & Garge, 2019).

The challenge of counterfeiting is in a state of constant transformation, driven by technological advancements and globalization. Notably, online marketplaces and e-commerce platforms have emerged as pivotal technological advancements that facilitate the illicit sale of counterfeit pharmaceutical products. The internet's cloak of anonymity has allowed counterfeit pharmaceuticals to access a global audience, making monitoring and enforcement of anti-counterfeit measures exceedingly difficult (ACA, 2023).

According to a study conducted by ACA on the channels used to distribute counterfeit pharmaceutical products, online platforms and supply chain infiltration constitute a significant portion, accounting for 40.9%. Additionally, the report acknowledges an escalating trend in online counterfeiting in the wake of the COVID-19 pandemic. It underscores the importance of establishing clear guidelines for product authentication and investing in technological solutions in line with a multi-stakeholder approach to combat counterfeiting (ACA, 2023).

2. STATEMENT OF THE PROBLEM

Online pharmacies have garnered favor among pharmaceutical consumers; however, the persistence of counterfeit pharmaceutical products poses a significant challenge. The Alliance for Safe Online Pharmacy (ASOP) has stressed the necessity for internet-based prescription drug vendors in Kenya to adhere to local regulations (ASOP, 2018). Counterfeit-fighting strategies deployed by the Pharmacy and Poisons Board (PPB) have yielded limited effectiveness. Consumers relying on authentication records to confirm the legitimacy of pharmaceutical products from online pharmacies face risk due to the centralized and alterable nature of backend authentication records, potentially leading to unreliable information. This study designs a smart-contract-based framework to enhance the anti-counterfeiting measures for online pharmacy products.

3. CURRENT ONLINE PHARMACY SUPPLY CHAIN

This paper focused on MYDAWA Limited, an online pharmaceutical store in Nairobi County, Kenya. This pharmacy is pivotal in handling prescribed and non-prescribed pharmaceutical products, acting as a vital link between prescribers, insurers, and patients. For non-prescription items, patients can order directly through the website or mobile app. However, patients must either upload a valid prescription or send it via email when it comes to prescription-only products. Upon receipt, the prescribed products are either added to the patient's shopping cart or dispatched directly (Cheon et al., 2021).

To uphold the security of the supply chain, MYDAWA meticulously sources its products exclusively from authorized importers. They also employ tamper-proof authentication stickers equipped with a scratch-off panel, revealing a unique number that can be transmitted via SMS to a designated short code for product authentication (MyDawa, 2022). It is noteworthy, however, that the backend data used in this authentication process remains under the exclusive control and maintenance of MYDAWA Limited. This data is not shared with any regulatory authority except for physical verification.

This centralized and editable record-keeping system allows for potential modifications, including the inclusion of pharmaceutical products sourced from unlicensed outlets, as described by Nyalita (2020). Such alterations can expose consumers to counterfeit pharmaceutical products through deceptive authentication processes.

4. CONCEPTUAL DESIGN

The framework design is illustrated in Figure 1 using a sequence diagram; the figure provides a detailed illustration of interactions between different participants in the proposed framework, the diagram demonstrates the activities and subsequent action that follows through. The interaction is divided into phases: Phase 1 is user registration, Phase 2 is enrollment of products, Phase 3 is product transfer, and finally, the sale of the pharmaceutical product and verification of product authenticity.

Each time information flows from one entity within the supply chain the details are pushed to the blockchain as transactional details including the address of output party and input party, transaction time, added information by the current participant and information from the previous block. The physical flow of pharmaceutical product is captured in the following phases of the sequence diagram;

Manufacturer: Sends a request to the regulator for approval, upon successful approval the manufacturer initiate the process of enrolling product to the blockchain network. The next phase, the Online Pharmacy request for transfer of enrolled pharm products, the manufacture initiate the transfer process upon receiving a notification for transfer, to complete the transfer of ownership, the Online pharmacy confirms that the products have been received, a function receiveProduct () is executed to realize this functionality. The final phase of the entire process is an interaction between the online pharmacy and the Consumer, the online pharmacy initiate the sale of pharm product to a Consumer upon receiving a prescription from the Consumer, the prescription is shared and stored off-chain to relieve the consumers of paying transactional fees while interacting with the blockchain, To verify the authenticity of the pharmaceutical product delivered by the online pharmacy, the consumer can use either the serial number on the package or the quick response code (QR) to authenticate the pharmaceutical product against the blockchain records.

In this paper, we employ the user authentication methodology introduced by Ali et al. in their 2019 study. This approach utilizes role-based authentication (RBA), categorizing users into distinct privilege levels assigned during their network enrollment process (Ali et al., 2019). Notably, RBA is implemented off-chain.

The framework incorporates a role-based structure within the traceability chain, where four distinct privilege levels are established. Drawing from the work of Peng et al., who employed Role-Based Access Control (RBAC) in a blockchain-based data privacy framework (Peng et al., 2020), this study applies RBAC to assign user roles.

The first user group encompasses the regulators, responsible for node registration, maintenance, block verification, monitoring the flow of product information, and ensuring accountability. The second user group consists of manufacturers tasked with enrolling products onto the blockchain and facilitating product transfers. The third user group comprises online pharmacy outlets that receive and transfer products to the end consumers. These consumers, classified under the "trace" access level, can trace back and authenticate products against trusted backend data records.

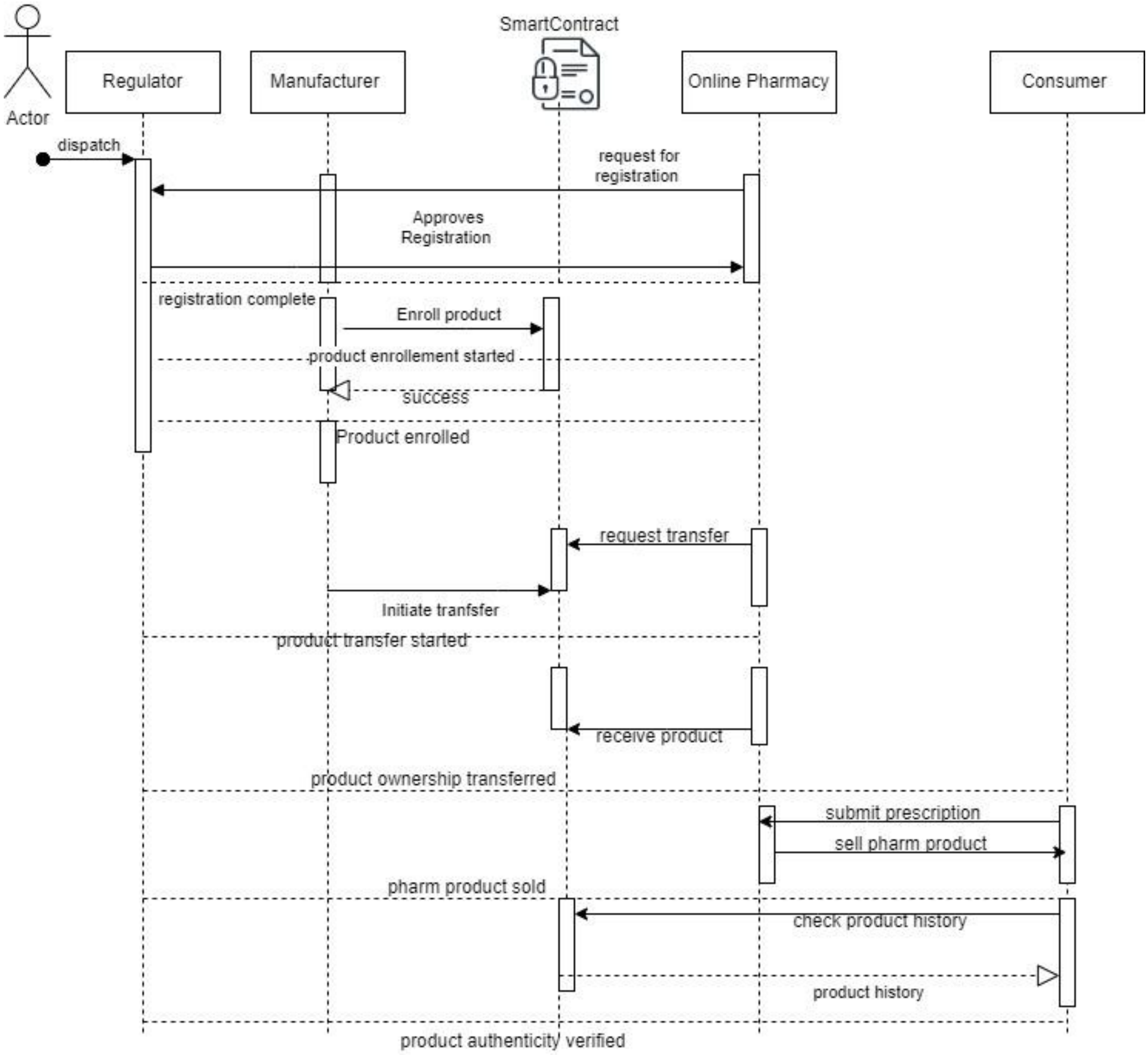

Figure 1: Sequence Diagram for the Proposed Framework (Author,2023)

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5. FRAMEWORK SMART CONTRACT DESIGN

The implementation of the Blockchain Based Framework for Online Pharmacy Product Anti-Counterfeiting was guided by the following Algorithms.

5.1 User Registration and Authentication Algorithm

NodesEnrolloment Contract {

}

The contract manages the enrollment of Network participants, including using the address and address for both manufacturers and online pharmacies. The contract is under the management of the regulator. Including the regulator ensures illegitimate manufacturers and online pharmacies do not register as supply chain participants. The following functions are included in the NodesEnrollment contract:

EnrollingNodes ()

The Manufacturer and Online pharmacies typically request enrollment on the blockchain by submitting the relevant registration documents off-chain per the guidelines provided by the regulator. Upon successfully meeting the guidelines, the regulator issues a unique prefix to the online pharmacy. The unique prefix is used to enroll the manufacturer and online pharmacy outlet to the blockchain network using the following details:

Address, Manufacturer_ID/Pharm_ID, pharm_ID (Unique prefix), pin_*NO, Name*

{

}

The function is used to enroll manufactures and online pharmacies, a single function is used to actualize the process since both manufacturers and online pharmacies is done using a similar list of attributes.

Pseudocode for EnrollingNodes ()

The pseudocode (Algorithm 1) is used to enroll blockchain users on the network, the framework only allows the regulator to enroll nodes into the network.

Algorithm 1

Input Data: (Address, Manufacturer_ID /pharm_ID (Unique prefix), pin_NO, Name)

Check if the sender address = = address_of_Regulator

Then

Enroll the node with (Address, Manufacturer_ID /pharm_ID (Unique prefix), pin_NO, Name)

Else

Generate error

End.

In the framework only the regulator can enroll nodes to the blockchain network, therefore the Algorithm must check if the caller address is similar to the address of the regulator before enrolling any new node.

5.2 Product Enrollment Algorithm

Only manufacturers enrolled and certified by the regulator have the authority to enroll products to the Blockchain Network, the manufacturer must be identified by the unique address. the requirement ensures Manufacturer M_1 do not claim the ownership of products belonging to manufacture M_2.

ProductManagement Contract {

}

The Manufacturer will manage the contract and include functions to manage the product information, including enrollment of products and ownership transfer. The Manufacturer creates a set of functions within the contract; the functions include enrollProduct () and transfer product

enrollProduct ()

Upon successful enrollment by the regulator, the Manufacturer initiates the process of product registration through a blockchain broadcast using the following details: OwnerID (address of the Manufacturer), batch_No, productName, product_Serial (Manufacturer_ID+serial), manufucture_Name, ownershipStatus, expiryDate. The function is invoked when the Manufacturer enrolls a product on the Blockchain network; all other entities involved in product circulation must reach a consensus to approve the registration request. The following algorithm is developed to implement the function.

Algorithm 2-Pseucode –Enrolling a Product on the Blockchain

Inputs Data:(Address, Caller_Add, OwnerID, Manufacturer_ID, batchNo, ProductName, product_Serial, productPrice, status)
If the Caller_Add = = Address //blockchain address

//caller address refers to address of the node (enrolling entity) sending the request

// the address of the enrolling entity is the same as the address of the owner

Enroll information to blockchain as

Insert (Manufacturer_ID, batchNo, ProductName, product_Serial, productPrice)

Set OwnerID= Manufacturer_ID;

Emit a message to notify the network of the new enrolled product

Generate firstBlock

Set status =’owned’

Else

Generate an error

rollback the contract to its previous state

End if

5.3 Pharmaceutical Product Flow Process

Along the supply chain, nodes participating in the flow process update information about the pharmaceutical product. The transfer of product ownership process and confirmation of transfer of ownership are treated as two different processes within the framework; by design, the requirement is implemented to avoid scenarios where the current owner sends the product to the recipient and the product by chance does not reach the intended recipient raising undesired trust issues within the network.

5.4 Transfer & Receive Product: Algorithm 3

The pseudocode is designed to ensure no trust deficit is experienced within the framework among the participating nodes, and the receiving node invokes it to ensure the complete transfer of the product.

Inputs Data:(Address, Caller_Add, OwnerID, pharm_ID, product_Serial, status, RecipientAdd)

If the Caller_Add = = Address //Blockchain address

//caller address refers to address of the node (transferring the product) sending the request

// if the address of the node transferring the product is the same as the address of the owner

If Status = = “Owned” then

Specify the recipient (RecipientAdd)//Blockchain Address

Enroll information to blockchain

Else

Do nothing

End If;

If RecipientAdd Exist

Update (Set OwnerID= pharm_ID)

Generate new Block with new information submitted

Set status =’transferred’

Else

Generate an error

rollback the contract to its previous state

End if

Blockchain linked as per the order

End If

5.5 GetProductsDetails –Algorithm 4

The function is invoked when the consumer queries the blockchain to obtain the details. The framework implements the query function as a view or a pure function to reduce the operational cost of the blockchain network; similar to the implementation by Saxena et al. (2020), pure functions in the blockchain network by design do not require gas for maintenance since the function do not modify the status of the blockchain. The function should return the product details enrolled by the **enrollProduct () function and** the additional information added along the supply chain.

GetProductHistory –Algorithm 4

Input Data (product_Serial)

Output: transaction Details of the product

If product_Serial Exist, then

Return: (OwnerID, Manufacturer_ID, batchNo, ProductName, product_Serial, productPrice)//scans a QR code or use printed serial on the pharm product to query
End If

5.6 Tampering with Product Information – Algorithm 5

The frameworks implement an algorithm to handle any attempt to tamper with the details of pharmaceutical products already enrolled on the blockchain network.

Tampering with Product Information-Algorithm 5

Input Data: counterfeitProductSerial, h1, h2

//h1 refer to the hash value of the previous block already committed on the blockchain

//h2 refers to the hash value of the block next block

If any participant tries to modify the product_Serial with a counterfeitProductSerial in Block h1
If h1. previous_block! = h2. Current_block then
Generate Error!!!

Else

Commits Next

End If

6. CONCLUSION

The suggested framework capitalizes on cryptographic hash functions within the blockchain to guarantee the integrity of backend data, a vital element in authenticating pharmaceutical products distributed through online pharmacies. Smart Contracts serve as the conduit for interacting with the blockchain records. The paper introduces pseudocodes for implementing each segment of the proposed framework; the framework is open for implementation, emphasizing its adaptability with various layer one blockchain and client application-based frameworks, allowing for the development of a minimum viable product.

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