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Procedia Manufacturing 42 (2020) 362–369

Procedia MANUFACTURING

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International Conference on Industry 4.0 and Smart Manufacturing (ISM 2019)

A decentralized application for the traceability process in the pharma industry

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Abstract

With the growth of a global market, new regulations aiming at preventing the fraud of counterfeiting drugs have been released all over the world. In the pharma industry, an innovative technology named serialization is becoming more and more popular as it allows to implement a packaging process based on a hierarchical aggregation. This guarantees that each box entering in the distribution network is marked with a unique identifier for an easy traceability by a central regulatory in charge to follow the life cycle of the product until given to the final patient.
In this scenario, the blockchain might offer a breakthrough proposing a decentralized and immutable traceability mechanism able to increase the security of the data and to reduce the success of a fraud attempt. To demonstrate the effectiveness of this technology, in this paper, a DAPP based on the Ethereum blockchain has been coded and tested as prototype in a pharma industry.

Peer-review under responsibility of the scientific committee of the International Conference on Industry 4.0 and Smart Manufacturing.

Keywords: Smart Contract; Serialization; Supply Chain; Distribution Network; Counterfeiting

1. Introduction

The pair "industry" and "blockchain" has started to animate the scientific debate as soon it became clear that the blockchain was not the Bitcoin [1] but a revolutionary technology that can transform the value chain of several industrial sectors [2].

Among them, the pharma industry is one of the most interesting and potentially favored beneficiaries of this revolution. In fact, all over the world, the pharmaceutical industries are heavily regulated to ensure their compliance to the highest quality and safety standards of the healthcare systems [3]. The quality of their products must be guaranteed not only during the production phase inside the industrial plant but, through their entire life cycle and along the distribution network until they are sold or administered to the final patient.

It has been estimated that counterfeit drugs cause over 100.000 deaths annually and over than $200 billion loss in the pharmaceutical industry [4]. In order to fight this phenomenon, the 2011/62/EU Directive introduces new regulations that can improve the effectiveness of the traceability process among the actors of the distribution network and prevent falsified medicinal products from entering into the legal distribution chain. To this end, the European Medicines Verification Organisation (EMVO) has taken the responsibility for advancing the creation of an

Peer-review under responsibility of the scientific committee of the International Conference on Industry 4.0 and Smart Manufacturing.
10.1016/j.promfg.2020.02.063

information system, the European Medicines Verification System (EMVS), that centralizes the operations of medicine verification and the enhancement of patient safety.

Blockchain could provide a breakthrough in this important process due to its inherent features that guarantee decentralization, immutability, privacy and security of data [5]. Companies have started to successfully experiment with blockchain protocols and networks [6, 7]. Based on blockchain platforms, smart contracts [8] represent one of the most promising blockchain applications as they enable two or more players involved in a common business to follow the rules of a previously specified process and track potential violations without the need of a central authority that regulates and controls the parties' actions.

In this paper, the authors propose the utilization of blockchain technology and smart contracts to automate, improve and strengthen the traceability process characterizing the distribution network of the pharmaceutical products. To this end, the implementation of a Decentralized Application (DAPP) tailored on the needs and on the packaging process of a local pharma industry, SIFI® SPA, has been realized.

The paper is organized as follows: section 2 presents a brief overview of the blockchain technology and some relevant use cases described in recent literature. Section 3 and 4 illustrate, respectively, the concepts of traceability process and serialization technology, main pillars of the 2011/62/EU regulations of the pharma industry. In section 5 the main innovations of this applied research are summarized: the key points that can favour the introduction of the blockchain technology within the serialization and traceability processes are illustrated and the prototype of the DAPP deployed within the test network of the Ethereum Blockchain (i.e. Ropsten) is presented. Conclusions, limitations and future researches are discussed in Section 6.

2. The Blockchain in brief and relevant use cases

A simple illustrative explanation of what a blockchain is provided by Murray in [9]. According to [9], a blockchain is a special database shared across a network of computers (called nodes). The nodes of the blockchain network are in charge to verify whether the new records to add to the database are valid; once a record is added, it cannot be modified. To achieve this goal, the nodes follow the rules of a consensus algorithm [10]. Moreover, the blockchain is encrypted such that only its owner can access "his" information. Last but not least, the nodes perform constant checks to keep the integrity of all the copies of the database. All these features make the blockchain a well-suited technology to guarantee [11]:

- Reliability of the network and availability of the database because the decentralized nature of the blockchain avoids the single point of failure. Also, the data is physically stored at geographic distinct places adding to system security.
- Security of the data that are stored using a one-way hash function is at this point in time impossible to reverse without knowing the private key that has been used to hash the data.
- Trust into consistency and integrity of the data which is achieved exploiting the consensus algorithm among the nodes of the blockchain network. Depending on the configuration of the blockchain system, trust can also be "decentralized" which reflect the fact that no central party acts as the sole "trust provider".
- Immutability of the data because the shared database cannot be modified. This provides the possibility of maintaining clear audit trails.

Nowadays, there is a lot of hype around blockchain, but some promising enhancements are under development. In fact, to unchain the potential of the blockchain technology, researchers and computer scientists are working on the conception of protocol variants that can address the main limitations of the original technology (e.g., consensus algorithm, transaction speed, block size, etc.) and even offer other features that may simplify the utilization and extend the adoption within several business fields.

Besides Bitcoin, one of the most famous and interesting blockchain is Ethereum [6]. In brief, the idea of the Ethereum is to offer a blockchain platform for implementing and deploying the smart contracts. A smart contract is a program that runs on the blockchain and has its correct execution enforced by the consensus protocol. A contract can encode any set of rules represented in its programming language and can be triggered by an event. Therefore, smart contracts can implement a wide range of applications, including financial tools, autonomous governance applications, education, B2B agreements and so on [12]. In the financial area, one interesting application is making money programmable.

One of the main application fields of this technology is the digitalization of certified data (which applies to several type of business cases). In fact, the blockchain technology can be used to store data safely and to eliminate the issue of the counterfeiting since all the history of the information cannot be tampered or modified. In [10] this type of application is discussed for the education sector and it is highlighted that many academic institutions have started to manage the students' certificates using the blockchain. In [5] the great advantages that can be brought within the healthcare system are listed. For instance, the medical treatment process can be strengthened because medical specialists can share several anonymous information and speed up the diagnosis of a patient disease. Moreover, it is potentially easier and – more secure from a data protection perspective – to trace the history of the patients' diseases and treatments. In [4, 13] several use cases belonging to the business of the pharmaceutical industry are analysed, demonstrating the disruption that blockchain will bring in this sector. In [14] the impact of blockchain technology in agriculture and food supply chain is examined showing the challenges and the potential applications that can favour the rise of blockchain. A recent contribution [15] presents a decentralized application for the traceability in the agri-food supply chain management the data produced by the IoT devices into the blockchain In [16] a debate which focuses on the adoption benefits in a sustainable supply chain is presented. More generally, the supply chain and traceability processes can benefit of the blockchain solutions [17, 18] increasing the trust of the information and the chain resilience [19] among the actors of the distribution network. As it will be shown in the following, this type of application is better discussed considering the regulations 2011/62/EU that involve all the actors of the distribution network of the pharmaceutical products, from the producer to the final client.

3. Traceability (2011/62/EU Directive)

Traceability is the ability to identify and trace the history of a product, keeping track of all the locations and of the users that have handled it.

In the pharma industry, traceability is an essential key at the basis of an improved trust-based relationship among consumers, pharmaceutical industries and all the actors of the distribution network. The prerequisite for the implementation of the 2011/62/EU Directive is that all the prescription drugs must have a unique identifier that allows a quick identification and, in this way, a safe withdrawn from circulation of the counterfeit drugs and falsified medicines [20].

Figure 1 shows the workflow of a distribution network process of a pharmaceutical company. It involves several actors and passages, including the dispatching to the final customer. Before entering a new product into the distribution network, the pharmaceutical company has to communicate to a central authority (in Europe is the EMVO) all the serial numbers of the drug package units that have been produced and ready to be shipped.

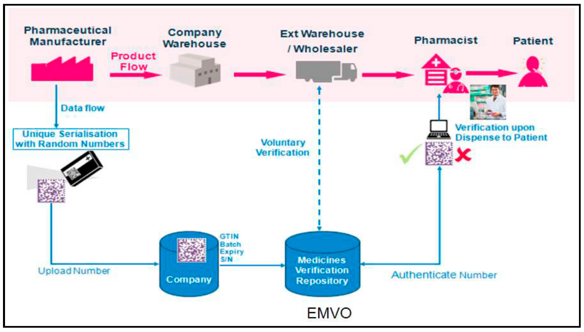

Fig. 1. Traceability process with a central regulatory.

The technological solution that allows the automation of this process is already in place in many pharmaceutical companies and takes the name of serialization. In brief, a serialization system is a collection of cyber physical systems that, cooperating together at the various levels of the production process, allow the automation of the packaging lines giving in output a pallet that aggregates a list of case boxes and unit boxes which are known to the system and that can be easily identified on the basis of the serial numbers characterizing each item.

Each actor (except the patient) of the distribution network is called to maintain for several years some of this information, in particular the one related to their individual responsibility. Moreover, all the main information concerning the production of a lot must be stored by the pharmaceutical company. Safety, security, confidentiality, resilience and reliability related to the quality of the product and its transactions throughout the lifetime and distribution chain must be guaranteed by the central regulatory.

4. Serialization technology

Serialization is that ensemble of smart technologies [21] that allows the packaging lines of an industrial plant to implement a packaging process based on a hierarchical aggregation. To achieve this goal and be compliant with the serialization specifications described in the 2011/62/EU Directive, each box of each level must be marked with a unique identifier. The codification of the identifier must respect several rules that depends on the packaging level (e.g., Unit Box, Case Box, Unit-Load), on the product packaged and, more important, on the encoding specification of the country in which the product will be traded.

As shown in Fig. 2, the marking of each box with a unique identifier allows to date back from the outer to the inner packaging level and vice versa, assuming that the packaging hierarchy is known and tracked in a computerized database. In fact, unit loads are not assembled randomly but according to the information carried by a work order. In a pharma industry equipped with a technological solution that supports the serialization, the packaging process is monitored by a real-time vision system that interacts with the other software (like the ERP and MES) and with the packaging lines. In this way, if the label of the serial number which has to characterize a box unit is not correctly printed, it is automatically discarded.

Fig. 2. Serialization and packaging hierarchy (unit box, case box and pallet).

Moreover, the vision system keeps track of the boxes that have been placed into each case and of the cases which have been placed into each unit-load. As soon the last level of packaging has terminated (generally corresponding with the lot unit load), the serialization software sends the hierarchy matrix list to the ERP that closes the work order and elaborates the beginning of the next phases (storage, batch release, delivery/shipping). During the batch release, the serialization software sends to the central regulatory the official hierarchy matrix list which has to be stored permanently in the database of the serialization software.

5. The Blockchain enhancement

As discussed in Section 3, all the other actors of the distribution network are called to maintain for several years many information about the drugs handled. According to this principle, every actor is responsible for its data and for the synchronization process with the central regulatory that must behave as central authority.

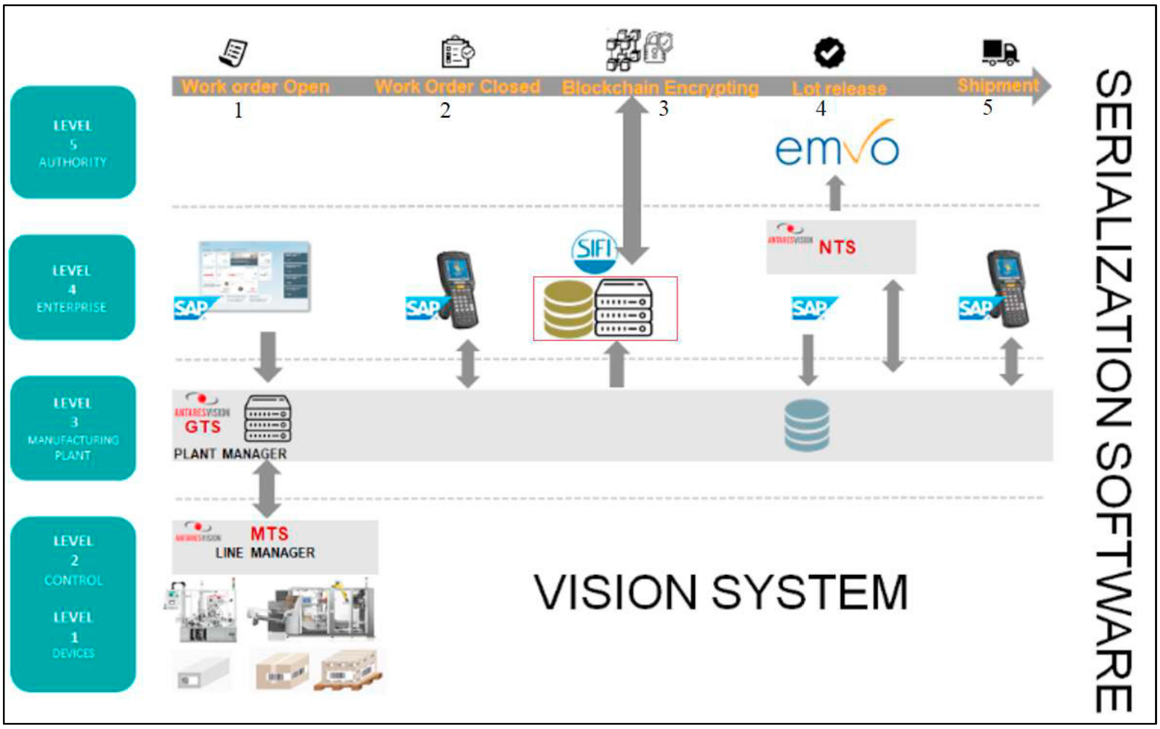

Fig. 3. Architecture of the serialization software and blockchain enhancement (courtesy of SIFI®). The BC Server is countered in red.

In this scenario, it is possible to identify the list of key features, required by the 2011/62 EU Directive, that can be handled and improved by exploiting the blockchain technology:

a. Ownership: every actor of the distribution network is responsible of a product as soon they receive it.

b. Uniqueness: every unit box of drug that can be sold separately must be characterized by a unique identifier.

c. Data synchronization: every actor is responsible for the synchronization process of their data with a central authority.

d. Data retention: every actor (except the patients) are called to maintain for several years the process information about the products handled.

A smart contract can support these requirements and, in the next subsection, the details of the prototype solution implemented in SIFI®, the industrial partner of this research, will be presented.

SIFI® is leader in the market of the ophthalmic products and it is specialized in the production of medical and surgical devices used in cataract surgery and diagnostic tools for ophthalmology.

5.1. Architecture of the serialization process with the blockchain enhancement

Figure 3 and Figure 4 show respectively the architecture and the communication protocols adopted in the serialization process of SIFI® SPA, integrated with the blockchain prototype application, main object of this paper.

The Levels 1 and 2 are constituted by the cyber-physical systems of the packaging lines that perform the serialization process with the aid of a vision system. These levels expose to the GTS Plant Manager of Level 3 all the real-time data of the field side, exploiting the communication protocols typical of the industrial automation, like OPC, IEC 104 and, ultimately, ODBC. On the other hand, the Plant Manager communicates with the SAP® ERP in order to handle the beginning (1) and the closure (2) of a work order. As already explained, any unit box worked in the packaging lines is labelled with a unique identifier (as required by the serialization specification) and stored in a database in order to be sent to the EMVO before entering in the distribution network when the lot is released (4). According to this information flow, it is possible to gather all these data and encrypt them into a smart contract of the blockchain (3). This task can be achieved by adding a server – from now on BC Server – at the Level 4 of the IT infrastructure that communicates directly with the blockchain network. In this way, all the data are securely encrypted and stored, and the company is relieved from the duty of maintaining this information in their systems, fulfilling the requirement of the data retention.

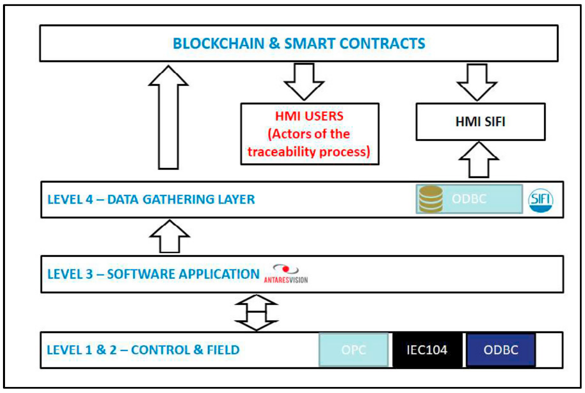

Fig. 4. Communication protocols involved in the process of serialization and blockchain encrypting (courtesy of SIFI®).

5.2. Implementation of the smart traceability process

The smart contract that encrypts all the relevant data of the serialization process has been codified in order to handle and strengthen the traceability process along all the distribution network.

The proposed traceability process allows to identify, at each step of the distribution network, the actor responsible of the good ("owner"). The owner is in charge to update the information concerning the status of the good as long it holds the ownership (for instance, the Pharma Industry is owner of a pallet as long it is not dispatched to the next actor of the distribution network). The good can be indifferently a pallet, a case box or a single unit box of product (see Figure 2) as it depends on the type of shipping and actor of the distribution network (e.g., a warehouse is likely to handle pallets, a wholesaler several case boxes and a pharmacy single unit boxes). In order to achieve such mechanism, the smart contract possesses, at least, the attributes and methods shown in Table 1 and 2.

Table 1. Attributes of the smart contract.

Name	Type
Product	Struct
Owner	Public Address

Table 2. Attributes of the smart contract.

Name	Input	Output
updateStatus	String	ProductStatus
updateOwner	Address	Owner

For what has been said, the smart contract can be developed such that only the owner can use the method of the smart contract for updating the status (updateStatus). Moreover, before dispatching the good to the next actor of the distribution network, the owner uses the method updateOwner to modify the value of the address of the attribute Owner and pass the ownership to the next actor who will be in charge to handle the good.

The variable Product is a struct that contains many unmodifiable information (e.g., name, class, expiration date, production date, serialization id, id of the outer package that it belongs to, etc.). In the prototype DAPP that has been developed, these data are set by an automated software routine running in the BC Server. In fact, as shown in Figure 5 and Figure 6, any time a product is packaged, the BC Server interacts with the smart contract to create an electronic identity (i.e., digital twin) of the item that is stored and encrypted in the blockchain with all the relevant information. Once the record is appended to the blockchain it can be retrieved and, eventually, updated using the unique identifier assigned by the smart contract and applied as a stamp with a QR code. The only internal variable of the variable Product that can be modified is an array of string, named Status. Any time the owner needs to update some information about the status of the good, the array is extended such that all the history of the good is tracked. In this way, any time the good (pallet, case box or unit box) has to be worked by the owner, the status information can be appended in the blockchain.

The application of this policy based on the ownership responsibility enables a mechanism that improves the traceability process and reduces the success of a counterfeiting attempt.

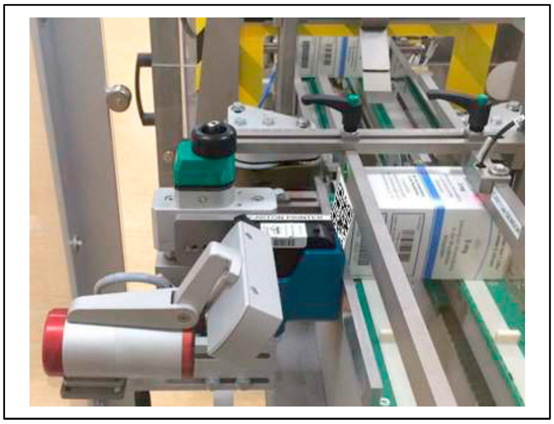

Fig. 5. Labelling phase of a unit box.

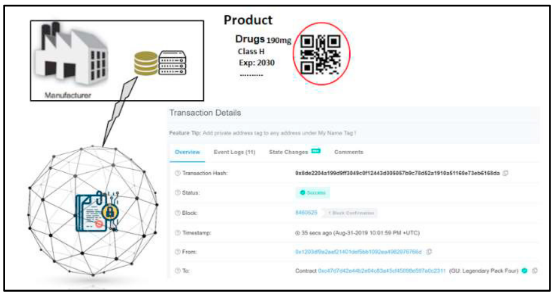

Fig. 6. Transaction operated by the BC Server encrypting the information of a product.

Figure 7 shows the locking mechanism operated by the smart contract to distribute the ownership token (T) among the actors of the distribution network. In this example, it is assumed that there are four actors in the distribution network. As soon the BC Server creates the electronic identity of an item into the blockchain (Figure 6), the corresponding good is packaged and labelled with the QRCode. With the same transaction, the smart contract passes the ownership of the item to the Pharma Industry (Figure 7.a) which is characterized by a public address.

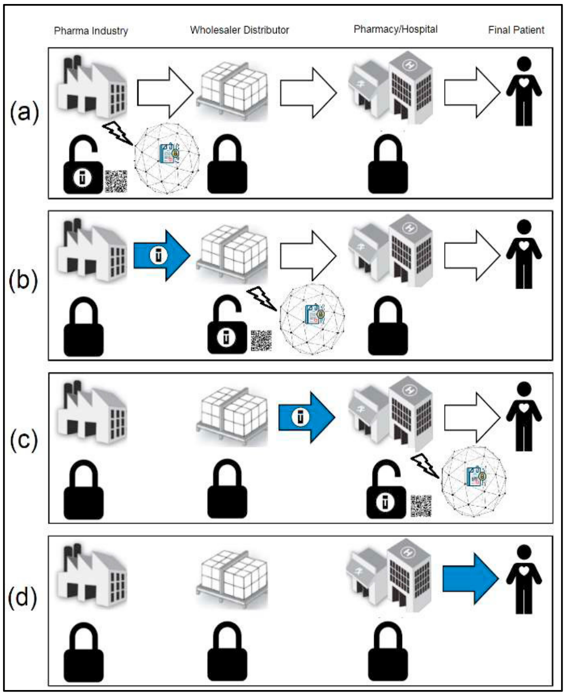

Fig. 7. Locking mechanism to pass the ownership token among the distribution network actors.

In this way, only the Pharma Industry can interact with the smart contract by the means of its private key. Before shipping the good to the Wholesaler Distributor, the Pharma Industry can append additional information about the status of the good and, afterwards, pass the ownership to the Wholesaler Distributor that is identified by a different public address. Once the good is received by the Wholesaler Distributor (Figure 7.b), this latter can add to the smart contract other information concerning the quality of the good received and, before the next shipping, pass the ownership to the hospital (or the pharmacy) that, acting as the last actor of the distribution network, will modify the status (Figure 7.c) with the information that guarantees that it is ready for being administered (or sold) to the final patient. Once the product is given to the final patient the token is destroyed and no one else can modify the status of the product (Figure 7.d).

The traceability process hereby described provides to the final client a powerful tool to verify the history of the product and check whether it was in the appropriate status to be sold. During the entire production and distribution process the transparency of the blockchain allows all actors to analyze the status of each product – but only if the actor has the knowledge about which blockchain address is owned by whom. This mechanism can prevent the counterfeiting attempts because only the owner has the chance of interacting with the smart contract and this mechanism is propagated forward to the final actor. Therefore, if at a certain point of the distribution network, a counterfeited product enters in the distribution chain, the forked path will not be traced in the blockchain because the forked actor will not have the grants to interact with the smart. In other words, the counterfeited good breaks the integrity of the distribution network.

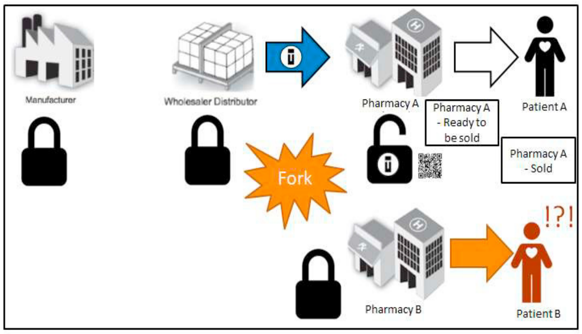

Fig. 8. Break of the legitimate distribution network.

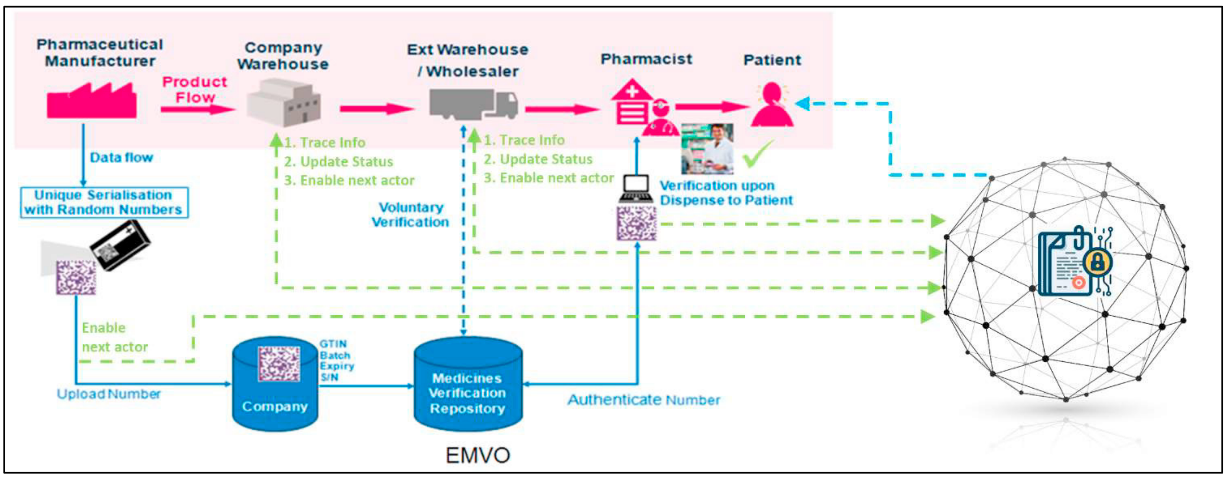

Fig. 9. smart traceability process taking advantage of the proposed blockchain-based solution.

This example is shown in Figure 8 where the Patient A can verify that the product purchased was "ready to be sold", as certified by the Pharmacy A, which is the legitimate selling point. On the other hand, the Patient B can visualize the same information shown to the Patient A understanding that (i) the selling point is not the Pharmacy B and (ii) that the product has already left the distribution network (because it was sold by the Pharmacy A).

The smart traceability process based on the proposed blockchain solution is shown in Figure 9. Any time a product passes to a new owner, the operations of 1) tracing info, 2) updating status and 3) enabling the next actor of the distribution network must be undertaken. This guarantees the tracking, the synchronization and the integrity of all the activities in the blockchain. Once deviations between the "real world" and the ledger on the blockchain occur, bad actors can be identified.

In any case, this process does not replace the one dictated by the 2011/62/EU, but it can be executed in parallel exploiting the DAPP prototype developed, object of the next subsection.

5.3. The Ethereum based DAPP implementation

The Ethereum blockchain offers several mature tools for implementing, testing and deploying a decentralized application. For example, the browser Metamask (available for smartphones and internet browsers) allows sending transactions to the blockchain.

Figure 10 shows the mockup interface of the prototype DAPP deployed in the Ropsten network of the Ethereum blockchain. Ropsten is a test network which resembles the character of the main net of Ethereum.

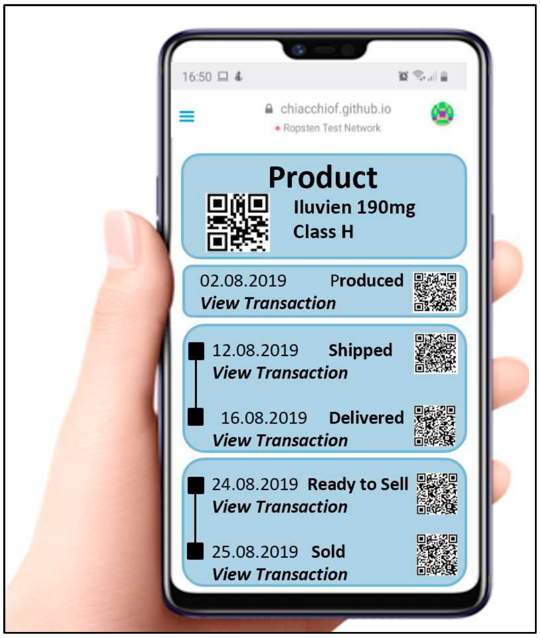

Fig. 10. prototype of the DAPP deployed in the Ropsten test network of Ethereum.

It is possible to see that the history of a product can be tracked from the beginning to the final stage by scanning the QR code printed in the package of the box unit. In particular, for each phase of the life cycle of a product, the DAPP shows the status, the timestamp of transition, the QRCode of the public address of the owner who entered the data (that is, who has signed the transaction) and a link ("View Transaction") that opens the Ethereum public webpage containing all the details of the corresponding transaction (directing to the block explorer on etherscan.io). In the example of Figure 10, the product was produced by the pharma industry on the 2nd of August and shipped on the 12th. On the 16th it was delivered to a pharmacy and on the 24th it was ready to sell. Finally, on the 25th it was sold to the final patient.

6. Conclusions

In this paper, a decentralized application for the traceability process of a pharmaceutical industry has been discussed.

Starting from the description of the severe standards that the actors of the distribution network of pharmaceutical products have to cope with, it was demonstrated that the blockchain can offer several advantages to simplify and strengthen the process of traceability throughout the life cycle of a drug and, more generally, of all the packaged units that enter in the distribution network.

To this end, the blockchain can be used to encrypt and store all the relevant information of a packaged product and track the handover among the actors of the distribution process, until the final patient. This simplifies the process of synchronization with the central regulatory, reduce the counterfeiting phenomenon and increase the trust of the users. Even more so, since the tracking data is not stored with a central entity, which could manipulate the data, the transactions in the ledger can be deemed trustworthy such that all actors can trust the data stored in the blockchain. The process of smart traceability enabled by using a blockchain solution is not limited to the pharmaceutical industry but can be applied to many industrial sectors that make use of a supply chain and a distribution network.

In this paper, the implementation of the proposed DAPP has been tested on the Ethereum Ropsten blockchain network able to run the smart contract. The smart contract was developed such that the concept of ownership of a good provides "true data" –allowing to secure the digital identity of the good.

The prototype application was tested in a packaging line of test. It was noticed that the production capacity of the real packaging lines can be drastically reduced due to the need to wait the transaction confirmation of the blockchain when a unit box is packaged. In fact, the QR code added on the unit box is printed only if the transaction returns successfully. This represents an important shortage of the current solution. In future research, we will investigate other blockchain platforms which allow for a higher transaction throughput and a lower latency than Ethereum.

Acknowledgements

This research has been supported by the research agreement (2018–2021) stipulated on the 26/02/2018 between SIFI SPA and the University of Catania.

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