

# The distributed ledger technology as a measure to minimize risks of poor-quality pharmaceuticals circulation

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**Background.** In the modern world, millions of people suffer from fake and poor-quality medical products entering the market. Violation of the rules of transportation of drugs makes them ineffective and even dangerous. The relationship between the various parts of the supply chain, production and regulation of drugs is too hard and has many problems. Distributed ledger technology is a distributed database, the properties of which allow us to track the entire path of medical products from the manufacturer to consumer, to improve the current model of the supply chain, to transform the pharmaceutical industry and prevent falsified drugs reach the market.

**Objective.** The aim of the article is to analyze the Distributed ledger technology as an innovative means of poor-quality pharmaceuticals prevention to reach the market as well as their forehanded detection.

**Methods.** Content analysis of web sites of companies developing Distributed ledger technology solutions had been performed. Five examples found with a google search engine by keywords "distributed ledger technology", "blockchain", "pharmaceuticals" and "supply chain" were examined. Analysis of relative scientific publications had been made. With the help of generalization and systematization methods, services provided by these companies were analyzed. The visual model of the supply chain was created with Microsoft Visio software.

**Results.** The analysis results contain a principle scheme of Distributed ledger technology implementation to achieve the objectives. The analysis of present-day pharmaceuticals supply chain structure and the distributed ledger technology capacities to improve pharmaceutical companies has been carried out and presented. Furthermore, the article allows getting acquainted with today's projects released to the market as well as the prognosis of the Distributed ledger technology potential in pharmaceutical industry enhancement in the future.

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## Abstract

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## Introduction

According to WHO statistics every tenth medical product in developing countries is non-conforming or falsified, meanwhile, the global size of this illegal market amounts to approximately \$30 bln[1]. The accident with the illegal release of falsified rabies vaccine was revealed in China in July 2018. As a consequence, more than 250 000 vaccines for children were released to the market[2].

To prevent adverse reactions during pharmacotherapy, governments around the world are tightening the requirements for tracking drugs and medical devices in order to slow down the global flow of counterfeit products. In the United States in 2013, the Law on Quality and Safety of Medicines (DQSA) was adopted, according to which until 2023 it is necessary to create an electronic, compatible system for identifying and tracking certain prescription drugs[3]. Thereafter, Euro Parliament Guidelines processed by Euro Commission to combat medical pharmaceuticals falsification went into force in 2011. According to the standard regulations, some obligatory elements of safety, e.g. a unique identification and safety control to prevent illegal disclosure were implemented into practice by February 2019[4]. In the Russian Federation The Federal law No. 425-FZ of 28 December 2017 on amendments to the Federal law on the circulation of medicines was adopted. In accordance with it, the system of obligatory marking with identification methods for all pharmaceuticals is to be implemented in medical means and released into circulation all over the Russian Federation territory. It will be obligatory since the 1 of January 2020[5].

The Distributed ledger technology is the best way to track goods at all stages, from the manufacturer to the consumer, it helps in the management of supply chains, solves the problem of trust and confidentiality.

The basic features of Distributed ledger technology are:

- information technology as a set of processes, methods of search, collection, storage, processing, provision, dissemination of information, as well as methods of implementation of such processes and methods based on the use of computer technology;
- information security.

These are two substantial digital areas. They include not only a peering network, a system of database construction and operation but also cryptography as a sufficient element of the system.

In accordance with the current ISO international standards, its numerous algorithms guarantee privacy, integrity, availability, authenticity, reliability, fault-tolerance and identifiability.

Distributed ledger technology is a distributed database, a sequence of attached and attaching block where every following block includes the value of the hash function of the previous block as hash information. All peers of the peer-to-peer network providing information exchange processes have the same sequence of blocks. A long chain called a transaction log is the result of blocks' interconnection (Pic.1).

Transactions are connected into blocks, where each block contains nearly multiple transactions that form a hash tree. Further, the block is transmitted to a Distributed ledger network where it is checked by all system participants to avoid mistakes and guarantee correctness.

Invariability (constancy) of a transaction log is guaranteed due to a hash function understood as a process of transformation of an array of input data of arbitrary length into a (output) bit string of fixed length.

Information architecture engineered and implemented allows adding information into a distributed database. Meanwhile it is impossible to change or delete data entered earlier to the previous blocks. It means that the implementation of various cryptographic methods, encryption mechanisms guarantee:

- a) transaction log constancy (invariability);
- b) authentication;
- c) data and network access control.

This ability to define the origin of data while guaranteeing their invariability makes Distributed ledger technology the most appropriate way to track medicine and medical products. The present study aims to investigate the Distributed ledger technology as a tool to track the entire path of medical products from the manufacturer to consumer. This work is intended for pharmaceutical market professionals and general public.

## Materials & Methods

*The process of the research Distributed ledger technology as a measure to minimize risks of poor-quality pharmaceuticals circulation.*

The research contains examples of companies that are developing Distributed ledger technology solutions in the drug supply chain. We defined the research question and created a visual model of the supply chain. The review has the following steps:

- analysis of laws from different countries for the production, transportation, and sale of drugs
- analysis of the current supply chain model
- analysis of problems in the standard supply chain model

- search and analysis of companies that provide Distributed ledger technology solutions in the supply chain
- data analysis and generalization of results

### *Analysis of the current supply chain model*

We will use the search terms "pharmaceuticals" and "supply chain" when using the electronic articles databases to systematically search literature, articles, and scientific publications for the last 7 years (from 2012 to 2019). Articles, and publications should discuss about introduction of Distributed ledger technology into the supply chain, contain information about the advantages or disadvantages of this technology and compare it with the current model; We will review conference materials and reports that comply with the review criteria.

Our goal was to review the narrow segment of scientific and public domain knowledge in the interconnection between pharmaceuticals supply chain and Distributed ledger technology solutions. Many successful projects do not have any grounding in research, hence our decision to include the conventional web search engines, where people in general showcase their innovation, often based on personal needs. While the literature typically reflects emerging applications and new trends, the supply chain tracking solutions market give a good indication of mature applications and functionality. In this study, we discovered different types of solutions, and our analysis was based on the goal to find common features between them.

The search was based on two main source types. The first source was online journal databases, indexes, and reference lists. We searched for prototypes and work in progress using the search terms 'supply chain', 'pharmaceuticals', and 'distributed ledger'. We constructed a search string using only the conjunction 'AND' operator to find relative information. The search was based on the metadata — that is, title, abstract, and keywords. We targeted both original research papers and review articles indexed by PubMed, Scopus, Web of Science and Google Scholar.

The second source was conventional web search engines. We searched these two source types—namely, the online journal databases and online websites—independently of each other. We searched the journal databases first, and then subsequently searched the related sites.

### *Definition of a research question*

How the introduction of the Distributed ledger technology into the standard model of the supply chain can prevent poor-quality pharmaceuticals circulation?

### *Legal aspects*

We will consider the legislative bases of the leading countries in the field of pharmacy and pharmacology - United States, European Union, Russia, and China. We will consider not only current laws and rules for the transportation of medicines but also research laws that are just about to be introduced, for better control of the tracking of medicines drugs on the market. We will use only official government sites of countries such as the U.S. Department of Health and Human Services, European Commission and Ministry of Health of the Russian Federation.

### *Criteria for reviewing companies*

We will consider only big companies with a large experience in the field of pharmacy, pharmacology and information systems.

### *Types of results*

We will create a visual model of the supply chain. We will also create a table with the benefits of implementing the Distributed ledger technology into the current model of the supply chain. Give a text analysis and conclusion on the current decisions of various companies.

### *Ethics and Dissemination*

As data collection was executed via published literature, ethical approval was not be required for this review.

## **Results**

Taking into account all the processes of research it's possible to state that a Distributed ledger technology can help solve current problems in a supply chain due to its properties and advantages. It guarantees traceability and transparency through all logistics of goods from a producer to the delivery location of medicines. The technology will allow controlling the progress of a product through serialization from the side of producers, distributors, and repackers. It provides a stable decentralized database with the possibility to use smart contracts. The database can be read and updated by all supply chain participants including wholesalers and patients. The guaranty of total transparency of a medicines supply chain and impossibility to change data in a Distributed ledger system restricts the possibility to commit fraud and raises confidence in a product with patients. It helps to identify and eliminate compromised medicines and can serve to the improvement of the period of validity and reduce waste created by expired pharmaceutical products. In Table 1 the benefits of a Distributed ledger technology implementation in a pharmaceutical product supply chain are stated.

## **Discussion**

As the medicines move up through the supply chain, logistics companies are to adhere to the guidelines of medicines handling during transportation and storage. Regulations may include maintaining the temperature and humidity range within certain limits. Environmental conditions of a supply chain can directly influence the quality and effectiveness of a medicine. For example, the system of a "cold chain" is implemented for temperature-sensitive pharmaceutical products such as a vaccine to guarantee high quality of immunobiological medical preparations, their secure and effective usage[6]. Thus, it's necessary to control all supply chain properly. However, taking into account the fact that every participant of the supply chain (a producer, a logistic company, shops, and drugstores) maintain one's database, that causes problems in tracking and identification of medical products. Due to its transparency, invariability and distributing nature the Distributed ledger technology provides the mechanism, that allows guaranteeing compliance with rules of logistics and transportation in a supply chain. Also, so-called smart contacts, computer algorithms whose aim is to sign and maintain self-executing contact for in a Distributed ledger technology environment can be used. They activate automatically under

certain conditions by notification of process participants in a supply chain[7]. Suppose that a case of temperature failure in the process of transportation was revealed. Due to the Distributed ledger technology the consumer can see the very moment of this failure. The process of an information collection concerning compliance with temperature conditions also can be automated with the use of a sensor working on the principle of the Internet of things and automatically sending information concerning the history of the storage temperature and the tracking system connected with distributed information exchange environment based on Distributed ledger technology.

The return of medicines is possible in the process of their turnover. It becomes possible in case of the surplus stock in the process of wholesale trade and it was necessary to return medicines unsold to the pharmaceutical companies. Although the share of returned medicines is low in comparison with sales (2-3% of all sales[8]). The sales volume of pharmaceuticals in the USA in 2016 reached \$ 450 bln.[9] According to the estimation given trade turnover of 2-3% from the total volume counts \$ 9-12bln. Instead of salvaging of returned lots of medicines that are of high quality and effective, pharmaceutical companies prefer reselling them. However, before having a chance to resell these goods being sold before, pharmaceutical companies make a legal commitment to guarantee the authenticity and quality of these products. The existing algorithm of work can be improved by implementing serial number accounting of medicines in a Distributed ledger technology system that serves as a decentralized and distributed ledger. Wholesalers and clients have an opportunity to check the authenticity of the package of medicines while getting connected with the Distributed ledger technology. As the medicines move along the supply chain, all transactions are written into the Distributed ledger technology thus there is a guaranty actualization of a distributed displacement register and its impossibility to be changed. It allows all participants to trace medicals at all stages of the life cycle.

The typical business model of a supply chain includes a number of participants such as the owner of a brand, manufacturer of dosage form, the wholesale trader, the retailer, the consumer and the regulator. All parties handle the same pharmaceutical and gain the same purpose to carry out effective therapy having low costs. Nevertheless, if two companies make mutual transactions going along with money exchange, the absence of sufficient trust causes the process cooperation held in accordance with the Procure-to-pay model and implementation of traditional tools[10]. Procure to Pay -is a multi-channel process connecting a client with one or numerous service providers or suppliers of goods and helps to conduct identification as well as authentication of parties in interest, raise an invoice, payment calculation, and others. Companies use such a long term and inefficient process to ensure that all data fit as there is no mutual trust. They need real evidence to account and enter goods, e.g. keeping both paper copies of the same transaction by a supplier and a client. Despite a buying order for a client and sales order for a supplier are the the same document, they are kept safe in different logs, both sides are to assure in the coincidence of the terms listed before in both documents. Thus, the existing process of data exchange is

inefficient and expensive. In such a long product life cycle the dataflow is often fragmented and financial costs are relatively high even if logistics were effective. The Distributed ledger technology will allow forming a new model of networking in the sort of trust-free model, all participants will be able to guarantee the data safety more conveniently, as it is shown in picture 2. With the support of more timely and accurate information flow, data can be transmitted simultaneously with other activities. Thus, each company can significantly improve the efficiency of its work and optimize its cash costs.

In the pharmaceutical industry, there are already several options for using Distributed ledger technology in supply chains: Merck (USA) in partnership with SAP (Germany) developed the SAP Pharma Blockchain POC application. This system is based on the existing solution by SAP not associated with the Distributed ledger technology, which is called SAP Advanced Track and Trace System for Pharmaceuticals (ATTP)[11]. It works on Android or iOS mobile devices, as shown in figure 3. It uses a simple barcode scan to see the location of medicines in real-time, wherever they are, including manufacturer, brand owner, wholesaler, and delivery[12].

When a manufacturer sends a batch of drugs, it registers the item in the SAP Pharma POC blockchain system. The system generates a unique identifier that stores four pieces of information coming from the ATTP: item number (based on GS1 standard), serial number, batch number, and expiration date. This ensures that the delivery information is kept intact and transparent. Other parties can get access to information from their local copy of the Distributed ledger technology system. On the distributor side, an application is used to scan the ID, which extracts the information from the packaging barcode. Thus, they can check any drugs returned to them that has a unique code.

Also in SAP added the ability to track each event, the transition of products to another owner. Thus, it is possible to track when the buyer purchases medicines. If the manufacturer receives a returned parcel with the previously used identifier, it is much easier to detect a fake. Also, there is a map that helps to make sure that the medicines are in the region in which you expect to find them[13].

Pharmaceutical company Novartis (Switzerland) is also experimenting with Distributed ledger technology since 2016 to identify counterfeit drugs and track temperature in real-time for all participants in the supply chain, using blockchain and IoT. This concept involves the use of a computing network of physical objects ("things") equipped with built-in technologies to interact with each other or with the external environment[15]. The purpose of their work is to use Distributed ledger technology to detect counterfeit drugs and track temperature with real-time monitoring for all participants in the supply chain[16].



Novartis is also currently engaged in the development of the network based on Distributed ledger technology for the consortium between the European pharmaceutical industry and the EU, which is called the "IMI Blockchain Enabled Healthcare program"[17] (IMI). The consortium will consist of companies engaged in Distributed ledger technology for small and medium-sized businesses, universities, clinical laboratories, hospitals, representatives of patients and others. It aims to investigate the use of counterfeit drugs, supply chain tracking, patient data, and clinical trials.

Another example is the VeChain system (China), in partnership with DNV GL (Norway) it uses Distributed ledger technology to improve pharmaceuticals tracking, monitoring, safety, and auditing. In 2016, the State Council of China issued the national information plan of the thirteenth five-year plan, which included Distributed ledger technology. VeChain is an approved supplier of Distributed ledger technology-based traceability systems in Shanghai and was given a task to implement traceability requirements in China by 2020. The VeChain traceability solution is being developed and tested in Shanghai and will soon be deployed throughout China.

In accordance with the VeChain system to track drugs and vaccines highly sensitive IoT devices collect and store in the Distributed ledger VeChainThor all the data connected with the production and transportation of vaccines, including vaccines from manufacturers, warehouses, distribution, cold chain (Fig. 4) as well as hospitals and even medical use of drugs. Ensuring the reliability of the data source, VeChain also eliminates the potential risks throughout the process and ensures that the records about vaccines are unchanging and permanent[18].

As an example of a centralized system and the use of cryptocode to fight against counterfeit products, it is possible to give example of the Russian Federation on the territory of which in the period from 1 February 2017 to 31 December 2019 the conduct of a voluntary experiment in the marking of the control (identification) signs and monitoring over the circulation of certain types of medicinal products for medical use is carried out. During the implementation of the experiment, a Federal state information system for monitoring the movement of medicines from the manufacturer to the end-user should be developed and put into operation[20].

The Center For Advanced Technology Development (CRPT) creates a unique digital code data Matrix and sends it to manufacturers and importers. The Data Matrix code is divided into two parts: the identification code, which determines the position of the goods in the system and the unified catalog of goods, and the verification code or crypto-tail, which is generated by the operator with the help of domestic cryptography technologies. Cryptocode is a set of additional characters in the Data Matrix code, which is applied to the packaging of goods. It is centrally generated by the operator with the help of domestic cryptography technologies and eliminates the appearance of "doubles" and the possibility of re-entering the market of goods.

Manufacturers put a code on each package of their goods. Through the digital code, anyone can trace the entire path of the goods from the conveyor to the online cash register which takes it out of circulation. The system records the transfer of goods from the owner to the owner at each stage of the logistics chain, which makes it impossible to "throw" forgery[21]. At the moment, applications for smartphones "checking the labeling of goods" allowing by scanning the QR code to obtain information about the origin of the packaging of the drug and make sure that the drug is legal, and it is available for free download[22]. This centralized product labeling and tracking solution currently has a number of shortcomings that the CRPT is trying to address. First is the length of the cryptocode Data Matrix, which is applied to the packaging of goods. Tests at the production facilities of various companies demonstrate that the mechanism with long code printing in some cases requires additional calibration and configuration of equipment to increase the density of code printing. Most attempts to print the data Matrix code with a crypto code on the package give the print quality below the required standards. This means that there are risks that the packaging is already in the process of turnover will cease to be read by scanners. Now the operator of the monitoring system determines the optimal size of the crypto code, which will provide the required level of protection. [23]

## Conclusions

Modern technologies allow demonstrating their capabilities and potential to transform the pharmaceutical industry. The features of the Distributed ledger technology are to provide unprecedented transparency of information, the immutability of the information entered and the efficiency of data management, strengthening trust and reputation. These advantages reduce the risk of a defective product entering the market and increase the effectiveness of its detection.

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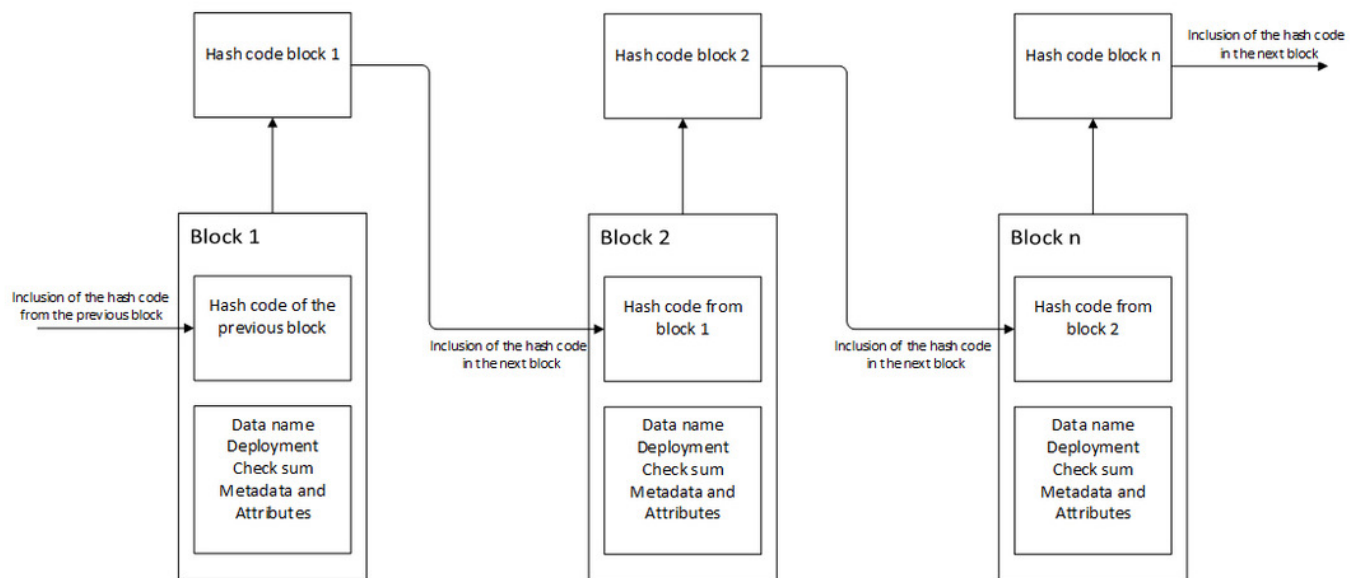
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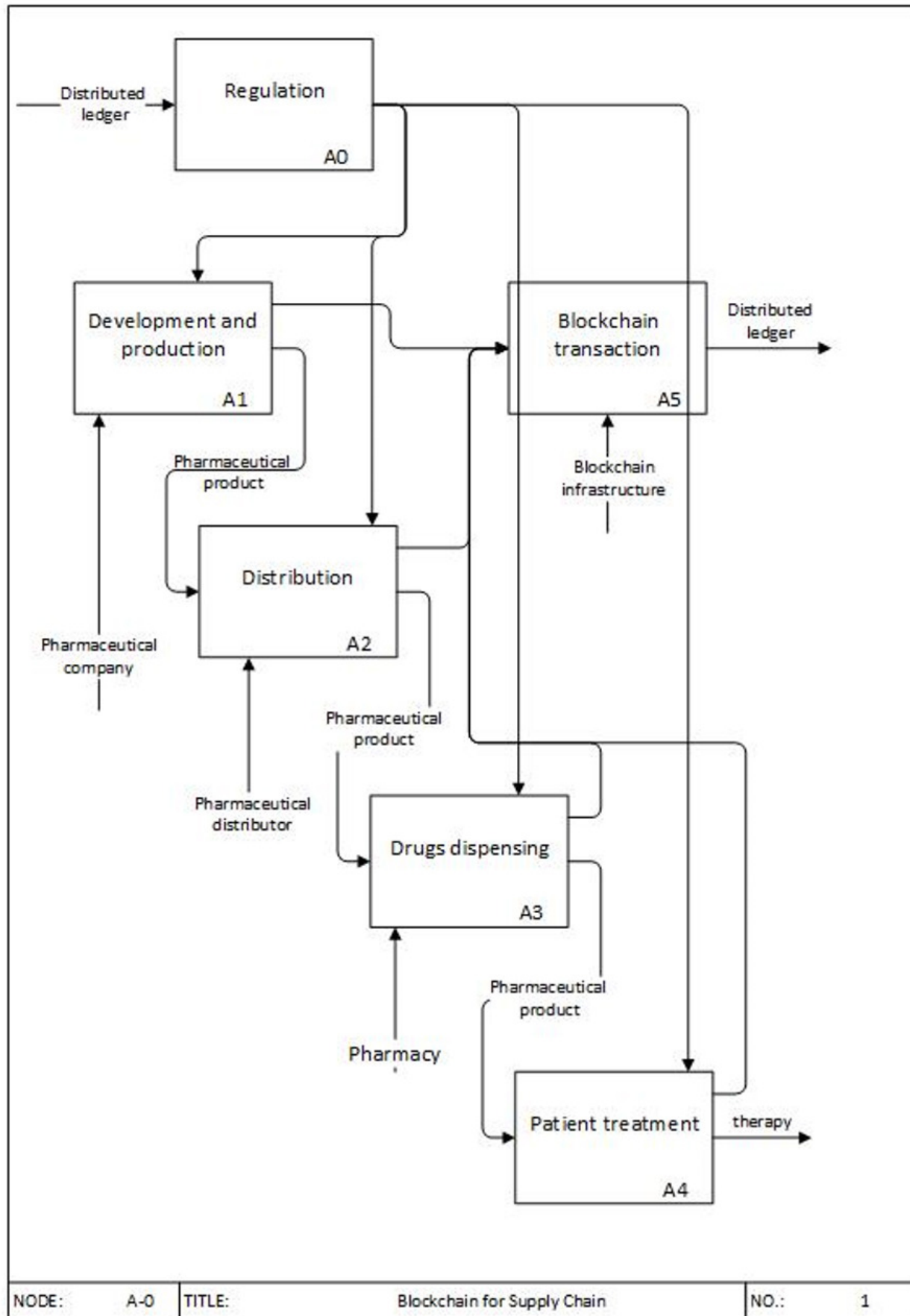
# Figure 1

Pic 1 The principle of Distributed ledger system operation



## Figure 2

Pic 2 The new model of networking

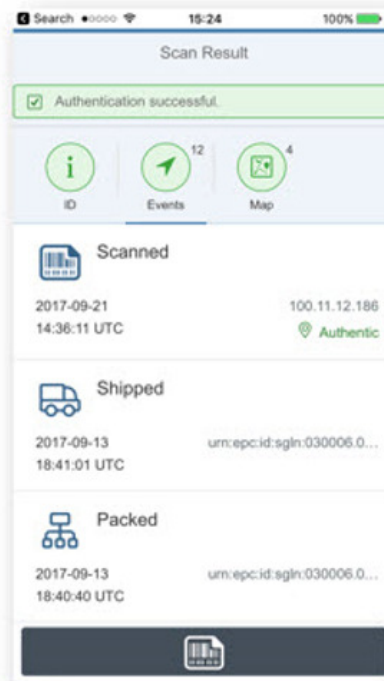


# Figure 3

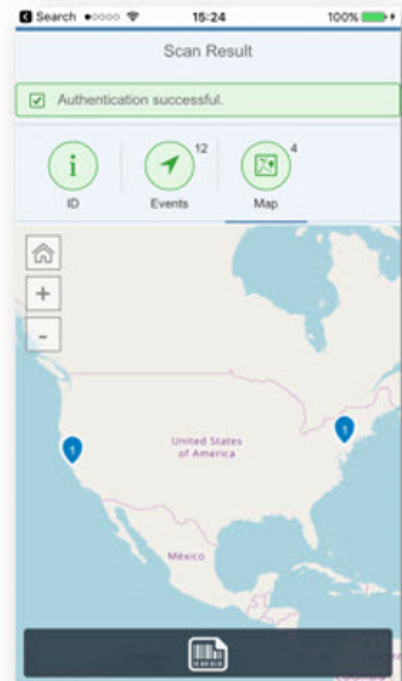
Pic.3 SAP Advanced Track and Trace System



**Product Scan**



**Product Audit**

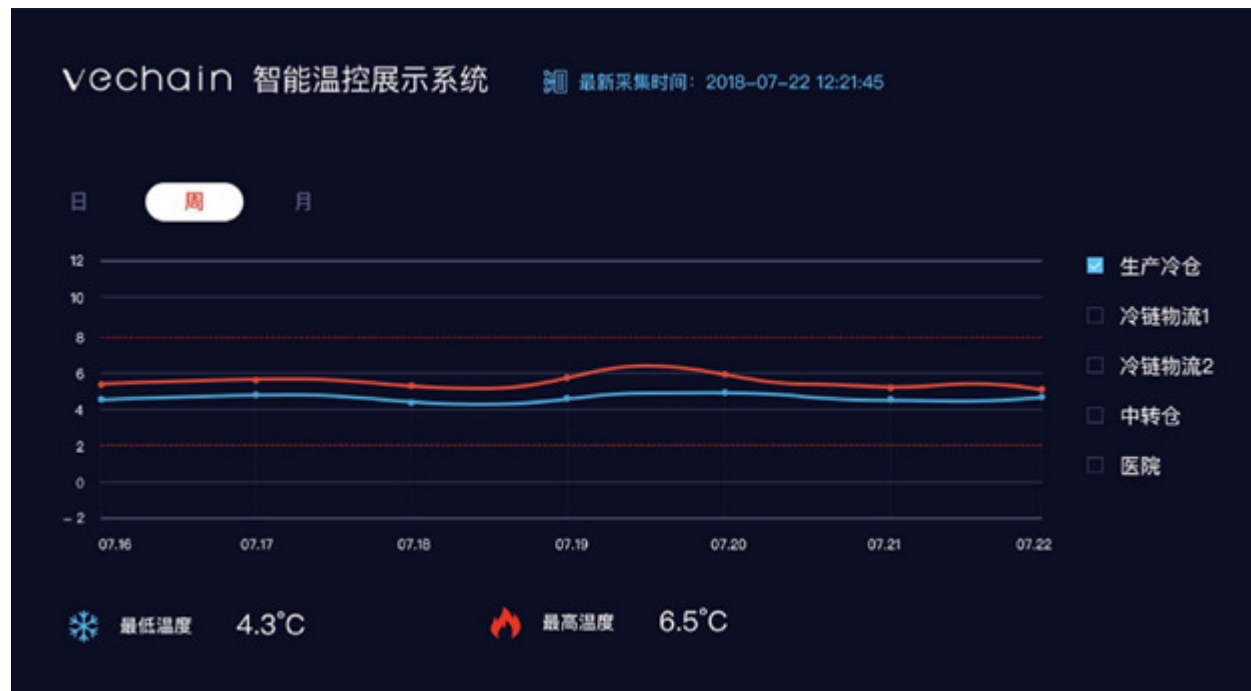


**Fraud Detection**



# Figure 4

Pic.4 The system of displaying of the temperature tracking platform VeChain



**Table 1** (on next page)

Benefits of a Distributed ledger technology supply chain support

1

Table 1. Benefits of a Distributed ledger technology supply chain support.

Name	Description
Effectiveness	Distributed ledger technology rises effectiveness of cooperation of all representatives involved into a supply chain through existing total trust
Audit	Guarantee full audit of a data log (the opportunity to trace the source of information)
Intermediaries	Cut the number of intermediaries of a deal
Defense	Defense the information in a data log from crashes and attacks as all data are saved in a decentralized way
Optimization	Optimizes the work and lower logistics costs through all the supply chain
Losses	Increases safety of goods, decreases the level of losses in goods delivery and storage
Production transparency	Guaranty transparency and authenticity of information about producers of goods and the process of distribution
Delivery transparency	Guaranty total transparency of medicines supply chain and impossibility to change data
Authenticity	Guarantee authenticity and quality of goods returned
Rights of a consumer	Guarantee the rights of consumers providing total and undeniable information about the origin of goods to be sold in retail
Custom clearanse	Decreases the share of gray (illegal) import and restricts possibility of fraud

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