

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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21

22 Abstract

23 **Background.** In the modern world, millions of people suffer from fake and poor-quality medical
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25 ineffective and even dangerous. The relationship between the various parts of the supply chain,
26 production and regulation of drugs is too hard and has many problems. Distributed ledger
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47 technology potential in pharmaceutical industry enhancement in the future.

48

49 **Introduction**

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

55

56 To prevent adverse reactions during pharmacotherapy, governments around the world are
57 tightening the requirements for tracking drugs and medical devices in order to slow down the
58 global flow of counterfeit products. In the United States in 2013, the Law on Quality and Safety
59 of Medicines (DQSA) was adopted, according to which until 2023 it is necessary to create an
60 electronic, compatible system for identifying and tracking certain prescription drugs[3].

61 Thereafter, Euro Parliament Guidelines processed by Euro Commission to combat medical
62 pharmaceuticals falsification went into force in 2011. According to the standard regulations,
63 some obligatory elements of safety, e.g. a unique identification and safety control to prevent
64 illegal disclosure were implemented into practice by February 2019[4]. In the Russian Federation
65 The Federal law No. 425-FZ of 28 December 2017 on amendments to the Federal law on the
66 circulation of medicines was adopted. In accordance with it, the system of obligatory marking
67 with identification methods for all pharmaceuticals is to be implemented in medical means and
68 released into circulation all over the Russian Federation territory. It will be obligatory since the 1
69 of January 2020[5].

70

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

74

75 The basic features of Distributed ledger technology are:

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

80

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

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

85

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

91

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

95

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

99

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

104 a) transaction log constancy (invariability);

105 b) authentication;

106 c) data and network access control.

107

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

113

114 **Materials & Methods**

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

117

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

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

- 124 • search and analysis of companies that provide Distributed ledger technology solutions in the
125 supply chain
126 • data analysis and generalization of results
127

128 *Analysis of the current supply chain model*

129 We will use the search terms "pharmaceuticals" and "supply chain" when using the electronic
130 articles databases to systematically search literature, articles, and scientific publications for the
131 last 7 years (from 2012 to 2019). Articles, and publications should discuss about introduction of
132 Distributed ledger technology into the supply chain, contain information about the advantages or
133 disadvantages of this technology and compare it with the current model; We will review
134 conference materials and reports that comply with the review criteria.
135

136 Our goal was to review the narrow segment of scientific and public domain knowledge in the
137 interconnection between pharmaceuticals supply chain and Distributed ledger technology
138 solutions. Many successful projects do not have any grounding in research, hence our decision to
139 include the conventional web search engines, where people in general showcase their innovation,
140 often based on personal needs. While the literature typically reflects emerging applications and
141 new trends, the supply chain tracking solutions market give a good indication of mature
142 applications and functionality. In this study, we discovered different types of solutions, and our
143 analysis was based on the goal to find common features between them.
144

145 The search was based on two main source types. The first source was online journal databases,
146 indexes, and reference lists. We searched for prototypes and work in progress using the search
147 terms 'supply chain', 'pharmaceuticals', and 'distributed ledger'. We constructed a search string
148 using only the conjunction 'AND' operator to find relative information. The search was based on
149 the metadata — that is, title, abstract, and keywords. We targeted both original research papers
150 and review articles indexed by PubMed, Scopus, Web of Science and Google Scholar.
151

152 The second source was conventional web search engines. We searched these two source types—
153 namely, the online journal databases and online websites—independently of each other. We
154 searched the journal databases first, and then subsequently searched the related sites.
155

156 *Definition of a research question*

157 How the introduction of the Distributed ledger technology into the standard model of the supply
158 chain can prevent poor-quality pharmaceuticals circulation?
159

160 *Legal aspects*

161 We will consider the legislative bases of the leading countries in the field of pharmacy and
162 pharmacology - United States, European Union, Russia, and China. We will consider not only
163 current laws and rules for the transportation of medicines but also research laws that are just
164 about to be introduced, for better control of the tracking of medicines drugs on the market. We
165 will use only official government sites of countries such as the U.S. Department of Health and
166 Human Services, European Commission and Ministry of Health of the Russian Federation.
167

168 *Criteria for reviewing companies*

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

171

172 *Types of results*

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

176

177 *Ethics and Dissemination*

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

180

181 **Results**

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

195

196 **Discussion**

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

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

219

220 The return of medicines is possible in the process of their turnover. It becomes possible in case
221 of the surplus stock in the process of wholesale trade and it was necessary to return medicines
222 unsold to the pharmaceutical companies. Although the share of returned medicines is low in
223 comparison with sales (2-3% of all sales[8]). The sales volume of pharmaceuticals in the USA in
224 2016 reached \$ 450 bln.[9]. According to the estimation given trade turnover of 2-3% from the
225 total volume counts \$ 9-12bln. Instead of salvaging of returned lots of medicines that are of high
226 quality and effective, pharmaceutical companies prefer reselling them. However, before having a
227 chance to resell these goods being sold before, pharmaceutical companies make a legal
228 commitment to guarantee the authenticity and quality of these products. The existing algorithm
229 of work can be improved by implementing serial number accounting of medicines in a
230 Distributed ledger technology system that serves as a decentralized and distributed ledger.
231 Wholesalers and clients have an opportunity to check the authenticity of the package of
232 medicines while getting connected with the Distributed ledger technology. As the medicines
233 move along the supply chain, all transactions are written into the Distributed ledger technology
234 thus there is a guaranty actualization of a distributed displacement register and its impossibility
235 to be changed. It allows all participants to trace medicals at all stages of the life cycle.

236

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

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

258

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

266

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

275

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

281

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

289

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

297
298 Another example is the VeChain system (China), in partnership with DNV GL (Norway) it uses
299 Distributed ledger technology to improve pharmaceuticals tracking, monitoring, safety, and
300 auditing. In 2016, the State Council of China issued the national information plan of the
301 thirteenth five-year plan, which included Distributed ledger technology. VeChain is an approved
302 supplier of Distributed ledger technology-based traceability systems in Shanghai and was given a
303 task to implement traceability requirements in China by 2020. The VeChain traceability solution
304 is being developed and tested in Shanghai and will soon be deployed throughout China.

305

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

312

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

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

328

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

346

347 **Conclusions**

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

353

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434 [chtoby-uskorit-vnedrenie-sistemy/](https://crpt.ru/crpt-podderzhivaet-iniciativu-farmotrasli-i-podtverdil-gotovnost-umenshit-dlinu-koda-markirovki-chtoby-uskorit-vnedrenie-sistemy/)

Figure 1

Pic 1 The principle of Distributed ledger system operation

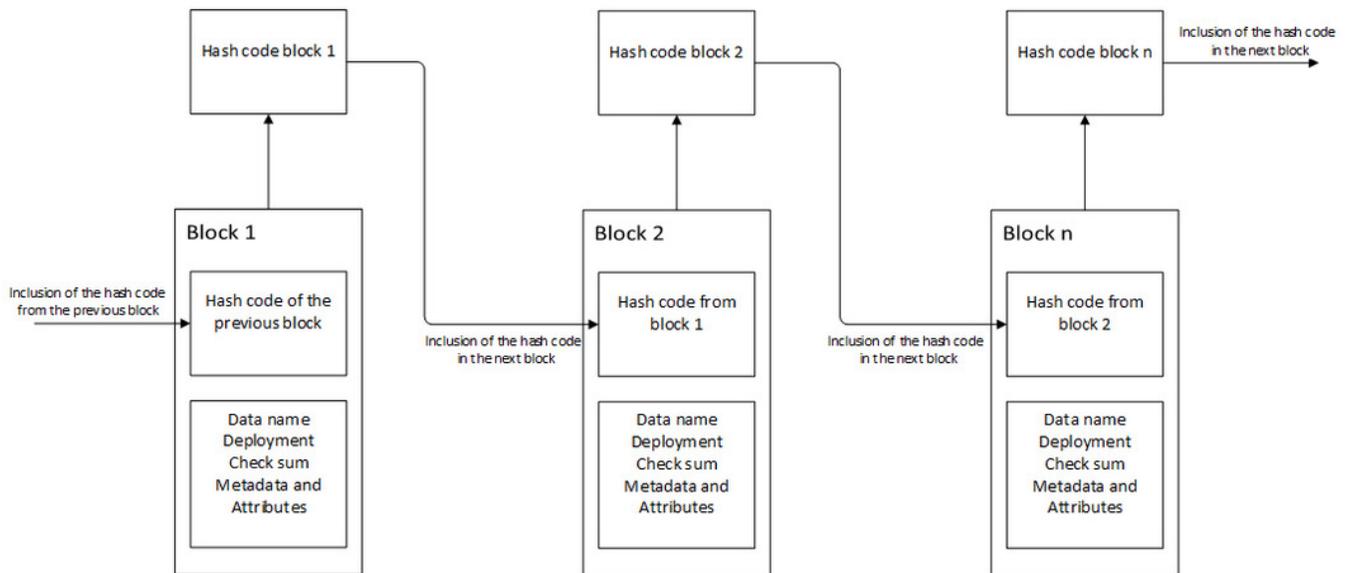


Figure 2

Pic 2 The new model of networking

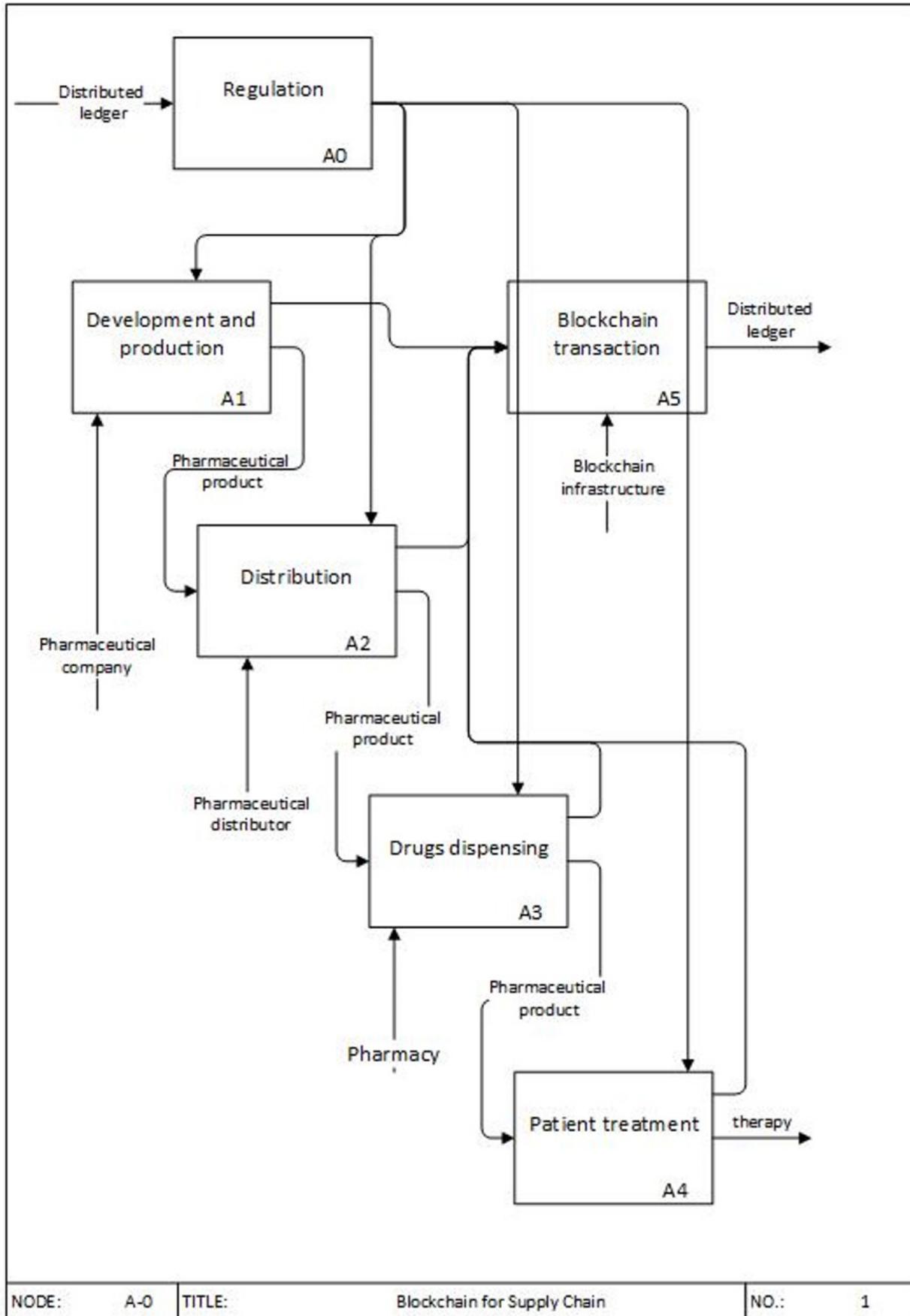
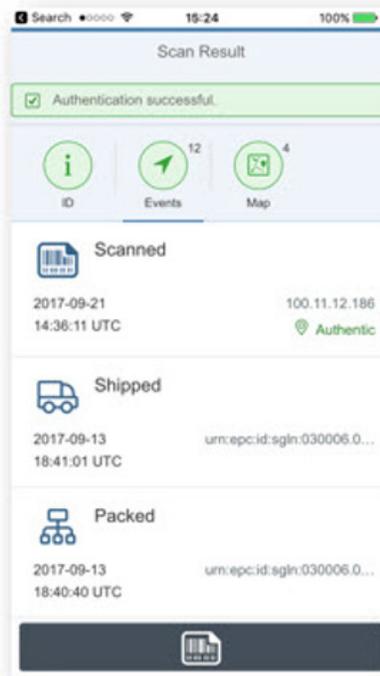


Figure 3

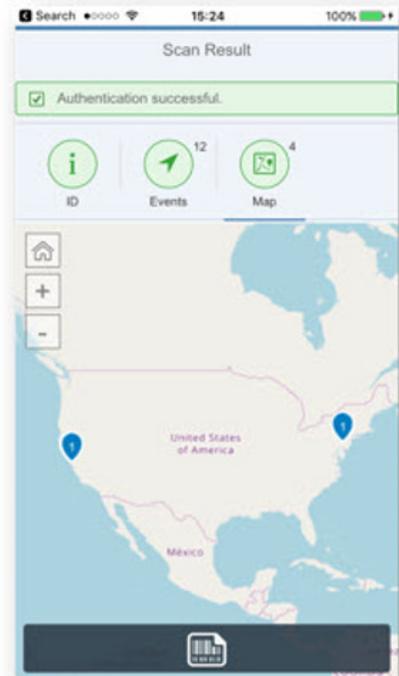
Pic.3 SAP Advanced Track and Trace System



Product Scan



Product Audit



Fraud Detection

Figure 4

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

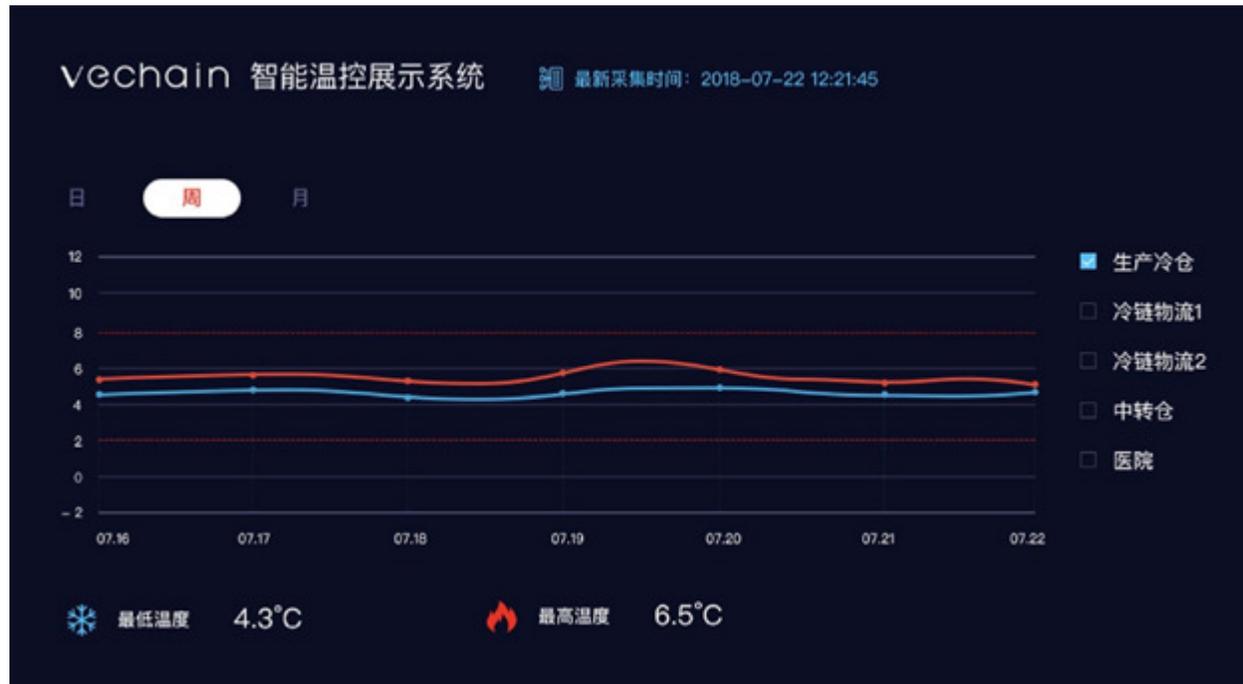


Table 1 (on next page)

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 clearance	Decreases the share of gray (illegal) import and restricts possibility of fraud

2