

Blockchain Technology and its Use in the Area of Circulation of Pharmaceuticals

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Abstract.

This paper looks into the prospects for the use of blockchain technology in the area of circulation of pharmaceuticals, provides a characterization of blockchain technology, and offers a set of examples and prospects for the use of blockchain technology in the area of circulation of pharmaceuticals.

Keywords: blockchain, blockchain technology, circulation of pharmaceuticals.

INTRODUCTION

We are currently witnessing the rapid development of blockchain technology, which is exhibiting promising chances of getting implemented extensively in the area of regulatory relations among entities operating within the market for pharmaceuticals. The shift to digital pharmaceuticals has found reflection in the digitalization of certain processes related to the circulation of pharmaceuticals within the strategically and socially significant market for pharmaceuticals. Blockchain technology is expected to benefit end consumers within the B2C market for pharmaceuticals in the following major area – confidence in the safety and efficiency of pharmaceuticals. It is expected to benefit market regulators and participants in terms of helping ensure the transparency of processes, save time and material resources, and foster fair competition across all stages in the circulation of pharmaceuticals.

A recent forecast by the international analytical agency Gartner lists blockchain technology among 10 major trends in the development of the international economy and finance as a new phenomenon that is capable of changing the global economy and finance. Analysts at Gartner have also suggested that blockchains could be employed in any sector where there is a need to verify transactions [1]. A report by the American analytical company Transparency Market Research estimates that the world market for blockchain technology is projected to reach \$20 billion by 2024. Researchers are founding their calculations on the consideration that in 2015 the blockchain market had a volume of \$316 million. The industry is projected to grow about 59% annually. The company Grand View Research has conducted a similar study, which suggests that in 2015 the blockchain market had a volume of \$509 million and projects the volume to reach \$7.74 billion by 2024 [2].

The purpose of the research reported in this paper is to determine some of the key areas for the use of blockchain technology in the area of circulation of pharmaceuticals with a focus on identifying a set of possible effects from employing it for the purposes of ensuring the proper operation of the market for pharmaceuticals. Of significance is also gaining a proper idea of the characteristics of blockchain technology.

The innovative technology is still far from maturity and, consequently, cannot be readily upscaled in the area of circulation of pharmaceuticals – it is only being employed in pilot projects for now.

However, the authors are convinced that sooner or later decentralization will start dominating the socially significant regulated market for pharmaceuticals, gradually supplanting centralized models of administration.

METHODS

Characteristics of blockchain technology

As a tool, blockchain technology was first employed in 2008 in the context of the bitcoin cryptocurrency. Currently, blockchain technology is going through further use and is being employed as a standalone technology in contexts involving financial transactions and contracts, as well as in areas like public administration, healthcare, science, etc.

A blockchain is a distributed database that contains information on all transactions carried out by the system's participants and can be used for the purposes of carrying out other transactions. In Russia, blockchain technology is referred to as 'distributed ledger technology' (DLT).

According to Dan and Alex Tapscott, the authors of the book 'Blockchain Revolution: How the Technology behind Bitcoin is Changing Money, Business, and the World', blockchain technology is a permanent digital ledger of economic transactions that can be programmed to record not just financial transactions but virtually everything of value to humankind [3].

All digital records are joined into "blocks", and are then cryptographically and chronologically bound into a "chain" using a set of mathematical algorithms. That is, each block that emerges in the system is closely linked with the previous one, and its name contains a time mark and a reference to the previous block. Encrypting guarantees the ability for users to change only parts of the blocks which are accessible to them, using private keys and codes that restrict access to the files. Encrypting also makes it possible to synchronize copies of the distributed chain of blocks across the entire base. The distributed ledger is stored with all of the system's participants simultaneously – i.e., there is no single place to store all registrar records. Blockchain virtually nullifies the likelihood of new unauthorized blocks being introduced and hacker attacks being perpetrated. The actual idea of blockchain implies a global decentralized system that will not depend on the legal situation in a particular country (<https://medvestnik.ru/content/interviews/Blokchein-klinicheskie-ispytaniya.html>) [4]. Here is what CEO and Chairman of the Executive Board of Sberbank of Russia Herman O. Gref had to say on the topic on May 21, 2016, at the Skolkovo business school: "In my view, blockchain technology is a new type of internet. It is an idea that is pretty much similar to the concept of the Internet" (https://www.bbc.com/russian/business/2016/05/160522_gref_skolkovo_lecture) [5].

Among the crucial benefits of the potential use of blockchain technology in the area of circulation of pharmaceuticals are the following:

– protection (the use of encrypting to confirm transactions);

- unalterability (the current state of a blockchain depends on previous transactions);
- transparency and common availability (based on public and distributed storage).

By ensuring the basis for employing decentralized forms of administration and entering into “smart contracts”, the new digital technology should significantly reduce and, based on the mass digitalization of the entire chain of circulation of pharmaceuticals, eliminate altogether the possibility of adulterated and counterfeit pharmaceuticals penetrating the market. Blockchain technology is expected to help preserve and maintain the health of the population and, consequently, ensure the country’s national security.

The use of blockchain technology in the area of circulation of pharmaceuticals

Federal Law No. 61-FZ ‘On the Circulation of Pharmaceuticals’ of April 12, 2010, construes the circulation of pharmaceuticals as activities related to the development of, conduct of preclinical and clinical trials for, conduct of examinations of, state registration of, standardization of and quality control for, production of, fabrication of, storage of, transportation of, import into and export from the Russian Federation of, advertising for, dispensation of, sale of, supply of, application of, and elimination of pharmaceuticals (http://www.consultant.ru/document/cons_doc_LAW_99350/) [6]. In other words, this is a regulated circulation chain that involves everything from the development of pharmaceuticals for the end consumer to their elimination.

A crucial area for the use of blockchain technology is pharmaceutical research. Blockchain technology will help pharmaceutical companies minimize their operational expenditure on the development of pharmaceuticals, while, ultimately, the use of DLT may help reduce significantly the cost of an end product. It is worth noting that currently the average cost of successful development of a pharmaceutical is as much as \$2.6 billion.

To ensure reduced timeframes and costs for the conduct of clinical trials for pharmaceuticals, the world’s three largest pharmaceutical companies Pfizer, Amgen, and Sanofi are currently engaged in developing a joint blockchain platform. The use of this new technology should help systematize all data on pharmaceuticals, providing access to data on patients who have given consent to enroll in clinical trials. A blockchain platform will make it possible to control the movement of pharmaceuticals, which, in turn, should help simplify the accounting process and, what is most important, eliminate the possibility of adulterated and counterfeit pharmaceuticals circulating (<https://miningbitcoinguide.com/technology/blokchejn-v-meditsine>) [7].

In June 2017, the U.S. Department of Health and Human Services staged the first pharmaceutical forum related to the topic – the Pharma Supply Blockchain Forum, which involved discussions concerning control over supplies across the entire chain of circulation of pharmaceuticals, quality control, the development of “smart contract” programs for the automation of processes, the planning of reserves, and the improvement of “last-mile” efficiency (<https://pharmvestnik.ru/articles/ne-chatlanskoe-eto-delo-prnt-17-m9-903.html>) [8].

Pfizer, in company with the bio-technological corporation Genentech and a number of major distributors, including many participants in the pharmaceutical industry, has launched a joint project, entitled MediLedger and based on the Ethereum blockchain platform, which will help control the entire chain from the manufacturer to the consumer. The project is intended to imitate market conditions for supplies. Contracting agents will work with their document blocks, putting together a

transparent history that will totally eliminate the possibility of adulterated products supplied into the chain [8].

Ambrosus, the world’s first and most reliable blockchain system for control over the supply chain, has announced its plans to partner with the pharmaceutical company Trek Therapeutics PBS (Trek), which specializes in the development of methods for treating patients for serious infections though the use of relevant pharmaceuticals. Ambrosus, which has in place a tried-and-tested blockchain protocol within global food supply networks, will carry out pilot projects with Trek to monitor the quality, security, and integrity of all stages in the pharmaceutical production process. As part of the pilot projects, the Ambrosus protocol will be focused on checking and keeping track of the entire production chain, starting with the use of primary chemical source materials. There will be several stages involving the synthesizing, cleaning, and checking of the active pharmaceutical ingredient (API), which then will be joined into a pharmaceutical. The product will be packaged, labeled, placed into proper storage conditions, and delivered to a clinical trial site. Trek’s co-founder and CEO Ann D. Kwong had this to say about the project: “Currently the pharmaceutical manufacturing process is highly regulated by pharmaceutical manufacturers and by regulatory authorities in an extremely labor-intensive and expensive manner. We hope to partner with Ambrosus to create a continuous monitoring and tracking system that will be less labor intensive, less expensive, and more transparent to all parties with a stake in quality pharmaceutical manufacturing” (<https://bitnovosti.com/2017/10/16/ambrosus-trek-therapeutics-partnerstvo/>) [9].

April of 2018 witnessed in Russia the launch of a pilot project on creating a system for monitoring the provision of regions’ residents with pharmaceuticals using blockchain technology. The project is aimed at eliminating the possibility of adulterated pharmaceuticals getting to end consumers; preventing malpractices related to and exposing the illegal circulation of expensive pharmaceuticals obtained with taxpayer money; preventing the making of changes to models for the treatment of patients. Thus, the system of prescription and supply of pharmaceuticals will be transparent both for patients and for inspection authorities. A joint blockchain project launched by Vnesheconombank and the Administration of Novgorod Oblast is the first project of this kind within the social sphere. It is expected to minimize risks for the most vulnerable categories of patients – benefit holders and people in need of costly treatment funded with taxpayer money. The platform for implementing the pilot project is the Novgorod District Clinical Hospital – a multifunction medical organization that provides a complete spectrum of medical services. Based on this, successful results from the project may be upscaled in the future into any medical organizations around the country. Here is what Chairman of Vnesheconombank Sergei Gorkov had to say on the subject: “We’re creating a whole new product by integrating three different technologies: an electronic prescription system, a subsystem for labeling pharmaceuticals, and resources from the Ethereum platform. As a result, we’re producing a service that is transparent and easy to understand for all participants in the process. A patient gets from a doctor a prescription with a QR mark, with information about it automatically getting into a single ledger, linking the patient’s data and the medication prescribed for them and including data on a specific package based on the label for the product. The patient is provided with the ability to monitor certain things, like, for instance, the product’s availability at the warehouse and data on the manufacturer and the release date, and at the moment they’re getting a pharmaceutical they can scan the product’s code to make sure that’s exactly what they need and confirm receipt of the package and its integrity. Thus, it helps resolve several issues at once that are a concern to most medical

institutions, and can often help save lives". It is also worth noting that the new technology will radically improve the accounting process by minimizing the costs associated with data verification and simplify the process of release of pharmaceuticals (<https://iz.ru/729269/tatiana-gladysheva/lekarstva-dobaviat-v-blokchein>, <https://gmpnews.ru/2017/10/v-novgorode-zapuskaetsya-pilotnyj-proekt-po-lekobespecheniyu-na-osnove-blokchejn/>) [10, 11].

The Petersburg project, which has been implemented with participation from the National Medical Research Center for Oncology, is aimed at the enhancement of processes related to clinical trials. Researchers view it as Russia's first ever project founded on the use of blockchain in the sector (<http://oncology-xxi.ru/about/events/klinicheskie-issledovaniya-onkopreparatov-v-rossii-perevedut-na-blokchejn/>) [4, 12].

A focus on maintaining control over the entire process of production of medicinal and chemical preparations based on blockchain technology has been pursued by researchers at the international research laboratory SCAMT at the Institute of Precise Mechanics and Optics jointly with developers of the Aira project and a group of IT specialists. The organization of a new process of quality control for a pharmaceutical is based on the use of a new product developed by the laboratory, known as 'Nanodoctor'. Owing to the developed system, by scanning the QR code specified on a product's packaging the end consumer will be able to keep track of all stages in the manufacture of the product and will be provided with assurance that the process has gone without violations and that the quantity of active ingredient is within the established range (http://news.ifmo.ru/ru/science/new_materials/news/7555/) [13].

Early 2017 saw the launch of a blockchain project aimed at combating the illegal production of pharmaceuticals. The use of DLT in relation to electronic product labeling systems enables the manufacturer to keep track of its own product. Pharmacological factories are interested in keeping track of their own products and having no unscrupulous competitors. The innovative technology will enable consumers of pharmaceuticals to keep track of the movement of products from the production venue to the drugstore organization using mobile devices or special scanners (<https://cryptonovosti.com/v-rossii-budut-borotsya-s-poddelkoj-lekarstv-s-pomoshhyu-blokchejn/>) [14].

The company ProfitMed has noted the edge demonstrated by blockchain technology over traditional software and has explored the use of the innovative product in relation to the product supply chain [8].

The potential use of the above technology is expected to gain a foothold across the various stages in the lifecycle of pharmaceuticals within the common market of the Eurasian Economic Union [15].

RESULTS

1. This paper has demonstrated that the use of blockchain technology in the area of circulation of pharmaceuticals should open up new vistas of opportunity both for business entities operating within and for end consumers served by the market for pharmaceuticals.
2. The paper provides an understanding of defining blockchains as a technology.

CONCLUSION

Thus the principal purpose behind the use of blockchain technology in the pharmaceutical industry is to create a single well-protected international registry that will store aggregated data on pharmaceuticals across the entire chain of their circulation. Given the distinct characteristics of a pharmaceutical as a product, it may be worth noting the need to explore a systemic approach to implementing the new technology in the area of circulation of pharmaceuticals. With its substantial characteristics, blockchain technology is expected to produce a revolution in the market for pharmaceuticals.

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