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Applying Distributed Ledger Technology (DLT) to the Pharmaceutical Industry

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The $963 billion USD pharmaceutical industry ("Pharma") continues to grow at an average compound growth rate of 7%, and its supply networks and systems are struggling to manage this ever increasing flow of goods. As an industry with high value and high consequence products - fakes can, and do, kill - it falls under specialist regulation and is under constant antitrust scrutiny.

With the introduction of the Drug Supply Chain Security Act (2013), the FDA has initiated a series of controls based around single unit tracking of pharmaceuticals. The first of these controls comes into force in November 2019, when the 2% to 4% of products that are returned each year (>58 million units[1]) must be verified before re-entering the market. DLT provides Pharma with a technical solution that is owned by the Community[2], is open to competition, adapts over time, to carry new products or fulfill future regulatory requirements, and provides the immutable record-keeping needed for complete adherence to FDA standards.

Authentag is uniquely positioned to build the services needed for the Track.one DLT for Pharma::

- Authentag has been asked to provide the services necessary for a DLT solution to both *Verified Returns* and future regulatory and inventory management needs by a broad spectrum Pharma at a meeting of the HDA and in subsequent bilateral meetings.

- Authentag already tracks products with the same type of unique identifiers and the same FDA scrutiny in 30 countries for 150 manufacturers of medical devices sold within the USA; technology that can be repurposed for use within the DLT.

[1] 2015 survey figures, provided to Authentag by HDA.org (industry CAGR was 7% from 2011 to 2015)
[2] See Definitions

- Authentag's management team has deep experience and proven expertise of logistics tracking, DLT, electronic ledgers, transactional technology, data control, and privacy protections.

This White Paper outlines the benefits Pharma will gain from a community operated DLT that ensures compliance and dramatically increased patient protection.

Introduction

This White Paper introduces the benefits of DLT to the Pharmaceutical industry and is an overview of the DLT Pharma project mandate.

A Community Owned DLT

DLT Technical documentation will be released that covers the function and connection details of any services designed and built by Authentag. As other community members make new services or replace Authentag's initial offerings those will also be shared in order to grow the DLT's scope and capabilities.

Context

On January 31, 2018, Authentag was invited by KPMG to present to the Healthcare Distributors Association (HDA.org), the trade group leading Pharma's efforts to implement the 2013 Drug Supply Chain Security Act (DSCSA) and modernize track and trace technology.

HDA's members represent 98% of the pharmaceuticals sold in the US.

HDA is tasked with bringing the Pharma community together to comply with FDA track-and-trace requirements, while protecting against anti-competitive/antitrust infractions. The first phase of regulations apply to the 58 million plus verified returns each year and come into effect in November of 2019. Subsequent controls tighten through to 2023 and include ever increasing numbers of counterparties and stakeholders.

Pharma concludes it needs DLT

This aggressive time frame has focused minds and efforts. By the end of the HDA meeting it was agreed that DLT was the best solution to meet stated requirements. Authentag has the the technical expertise and relevant experience required to achieve this.

Legal

Stuart Corby is a Founder of Authentag LLC[3] and a systems and business architect. This work is covered by creative commons 4.0 International License. Caveats:

This document is primarily about the technical business implementation of DLT to the Pharmaceutical industry and is based on the authors experience of physical asset tracking, of implementing community wide transactional technology standards from the financial industry, and from specific experience in DLT (Blockchain) gained as technical advisor to hdac.io (backed by Hyundai) a public private blockchain built to manage message traffic and transactions between Internet of Things IoT devices.

This paper was written with a large amount of help from members all across the pharmaceutical and blockchain industries. It is for informational purposes only, a draft, that wants and deserves to be updated as industry needs change.

As a community based project, built for the community I have endeavoured to take as many of the concerns and requirements expressed in industry meetings, bi-laterally to Authentag and in person to me over far too many coffees, into consideration in the construction of this paper, while adopting many of the lessons learnt through work with our tech teams at Authentag.

It is expected, and welcomed, that the community will require ever more of their transactional technology and as industry experts increase their engagement they will offer refinements to the DLT.

Advantages of using DLT

[3] Authentag was founded in 2014 and has been securely recording the movement of uniquely identified physical items on electronic ledgers since January 2015. For clarity: Authentag currently does not use Proof of Work or Proof of Stake or any forms of a technology that would distribute its ledgers without centralized control as the industries it currently serves do not need this technology to operate (and previously it was technically inadequate to provide the transactions speeds necessary) Authentag does however use the other key building blocks of a DLT and has vast experience of creating immutable continuous chain of custody records for physical items.

There are a variety of factors that make Pharmaceutical *Verified Returns*, track and trace, and inventory management a perfect match with modern distributed ledger technology.

Proprietary Data Protection

Using DLT architecture for Pharmaceuticals will allow the community to track the state of a labelled product over time without exposing proprietary data to the whole community.

Controlled data access

Any product, manufacturer or distributor identifying data will be encrypted and can be limited to allow access to the inquiring and verifying party, or only the parties they see fit to allow access to that particular transaction.

A true DLT is not owned or controlled by any single party

The DLT is not owned by any entity; access is controlled, but anybody in the community can use it once the rest of the community accepts that they are a valid participant, and that they are technologically competent to join.

DLT connects you to the whole community

Placing DLT at the heart of the community significantly reduces the complexity of maintenance and the number of connections large scale manufacturers and distributors will need to maintain.

Multiple solutions depending on member requirements

DLT allows community members to build, lease, buy or share nodes (electronic services that come together to make a DLT) as suits their needs and capabilities. In the DLT community envisioned by Authentag, all participants will be able to build their own nodes, pay others to create nodes for them, or pay for services from a third party who owns or leases nodes on their behalf. This is possible as all information on what each service should achieve and how it should connect will be open source, and shared with the community.

For nodes that are needed for the whole community there will be a governance system that allows the community to vote to replace any one provider with a suitable alternative.

For nodes to be authorized to join the community, the owner of that node will have to subscribe to the community and pass business identification and automated security vetting.

Payment for participation

Once part of the community, nodes will be able to rent their services to the community and receive micropayments for doing so. This allows community nodes to generate revenue to recoup their costs.

Adaptable to new requirements

The messages that are sent between the DLT community members are contained in smart contracts. These contracts will contain 'in the clear' and encrypted contents to protect the confidential information while facilitating the tracking of state changes of items owned by members of the community. Smart contracts are small pieces of software, so as the needs of the community change and as regulations increase they provide the flexibility the DLT needs to adapt. Contracts can be bilateral or multilateral and can trigger other contracts stored on the Distributed Ledger.

Data resilience and immutability

The nature of a distributed ledger is that it resides in multiple places at the same time on 'Full nodes' and that each of these copies is guaranteed to be immutable (identical and unchangeable) by the DLT. Encrypted information in contracts would only be available to those that hold the keys but everyone with a full node has a copy. Distributors can put full nodes in close physical proximity to where they perform their verifications, even if they are in multiple locations. Manufacturers can maintain persistent, real-time 'disaster recovery' full nodes to ensure data integrity or they can rely on the community to protect them.

Authentag's pledge to the community

Authentag will build all the services needed to execute *verifiable returns* using DLT and will do so with a view to complying with existing and forthcoming regulations and industry concerns about managing inventory in general.

Cloud SAAS Services

The DLT must serve a vast array of community members, from large to small. Authentag will provide paid cloud services for smaller community participants to connect in order to manage their returns in a cost efficient manner.

Bespoke SAAS service	Larger community members, who do not wish to build their own infrastructure, will be able to lease nodes maintained by Authentag.
Community to community services	Authentag will provide a multiverse node to connect to any other community service that verifies returns - this multiverse node will respond to requests for verifications and bill the inquiring party for those requests in order to pay for the community services needed to execute the verification. Other communities will be responsible for building a suitable gateway to connect to the multiverse node.
Prenuptial option to replace Authentag	Authentag will provide all information needed to describe what each service should achieve, how it should connect and how it will pass validation to join the community (testing protocols) to allow anyone else to build the same service (and replace) any or all of the services Authentag will provide to the community.
What the DLT will track	All pharmaceuticals shipped now carry a unique identifier in the form of a machine readable data-matrix. This data-matrix contains a GS1 compliant code called a Global Trade Identification Number (GTIN) and a series of Product Identifiers (PI) that make unique, packet level identification possible.
GTIN Lifecycles	The DLT will track the lifecycle of these GTINs by allowing smart contracts to update their status, recording the interactions of uniquely identified nodes with the immutable time stamp of that interaction. *This is based on Authentag's US Systems Patent 9,076,024 for tracking any uniquely labelled physical item from production to end use.*
Protected Unique History	Signatories to the smart contracts will be able to reference every interaction with the same item in order to see its full history. Third parties will not be able to tell the nature, contents, frequency or identity of the tracked item as this information is locked within each contract.

Built in Flexibility through Smart Contracts	This basic foundation will allow trading partners to issue more complex, bilateral, multilateral or hierarchical smart contracts which will allow them to solve business issues beyond the remit of this whitepaper.
Pricing	The Pharma DLT must be affordable for all participants and provide services that are fairly priced no matter the size of the participant. Pricing needs to respond to increase in usage while maintaining enough income to support the community services needed for the DLT to function.
Subscription Fee	There will be a (Fixed) cost to be a part of the community
Activity Fee	There will be a (Marginal) cost to execute a contract.
Income	Those providing services to the community will receive a (Marginal) payment.
Volume Authentag's pricing over time	This pricing structure ensures that all community members pay towards the running of the community but that the smaller community members do not subsidize the high volume users of the community.
Prices are set by the community	Prices are set by the community through a voting procedure. If the community sets the price too low then service providers will withdraw their services. If the price is set correctly then there will be competition to provider services within the DLT.
Technology underlying the DLT	All DLT is built on technology that has been improved over many years including encryption, hash trees, gateway integration technology and small self contained packets of code that can interact with each other (now known as smart contracts). Using these basic building blocks, the innovation is how DLT's keep multiple copies of the same electronic ledger without a central

authority.

Private Blockchain solutions aren't suitable

The process of how this is achieved is a vital requirement for the Pharmaceutical industry. Private blockchains often use a central, controlling authority to decide who gets to write the official ledger (that all other participants then copy). This solution is useful to many large corporations but the pharmaceutical community cannot choose one supplier or provider who can then control the system for them. This means they are no longer fully distributed and turn the controlling interest into a network provider. This would run foul of antitrust concerns and would divest poAuthentagr from the existing members of the community to the company that ran the private blockchain for them.

The case for Delegate Proof of Stake (DPoS)

The DLT chosen by Authentag is a proven technology based on Delegated Proof of Stake (DPoS) which allows for high transaction rates, with low latency of contracts that can be complex in nature. This is vital in order to provide the response times needed for distributors to check product in real time, but also to handle future billing, invoicing, financial structure and regulations that are all addressable when you have single unit accounting of physical product.

DPoS means the DLT isn't controlled by a single party

DPos is the only solution that has undergone the rigours of real world usage and can be managed solely by its members once it is created. This community governance prevents any loss of control by the community to a single provider which, in turn, alleviates antitrust concerns. Community members can make their own services or outsource their creation to any external party they choose. Community services can be offered by any service provider, and voted into use (and out of use) by the community. There is no entity that 'owns' the DLT, network or blockchain.

Speed and transaction rates

Technical testing[4] of the chosen DPoS has shown response times of less than one second for up to 50,000 transactions on their infrastructure (exceeding industry requirements).

[4] David Moss EOS.io 23rd January 2018

How speed is attained

Our chosen DPoS takes three seconds to generate a single block. To allow accounts to communicate within a block (and not wait up to three seconds for the next block to get a reply) the blocks are split into cycles with transactions recorded in a thread on that cycle. Any transaction can then be responded to in the next thread, whether that is in the same block or a new block

Private Fork of the Public Block

After initial set up is complete, a private fork for the Pharmaceutical industry would be the optimal technical solution. This fork would have controlled 'permissioned' access and allow governance to be limited to only pharmaceutical community members - it will also increase the transaction speed to the industry by only dealing with pharma related traffic and by geographic location of block producers in locations where internet connectivity can be optimized while disaster recovery and data resilience can be maximized. This process would be controlled by members who can vote of the delegates they prefer to use based on their speed as Authentagll as other factors.

Controlling access to the DLT

As no one entity owns the community, processes need to be in place in order to onboard a new member and grant them an account.

- Authority - Is the new member genuine? Do they exist, what is their role, are they qualified to join by the business they pursue or services they offer?
- Payment - has the member paid their dues? (Dues are then split up to pay for the community services needed to operate the DLT)
- Technically competent to join? Has this member passed automated testing, will their node perform the actions or services it claims to perform without endangering other members of the community

Existing, trusted members of the community would provide these services for a fee. Again, the community can vote to replace them if they are not happy with their competence.

Within an account, hierarchies can be set to control actions. Actions can require multiple sign offs to be sent to the chain or can be sole sourced. The Pharma DLT uses account hierarchies to control who can issue new accounts under a company, who can issue contracts and who can sign contracts. At a user level it can also force multiple

signatories to authorize any new user or a password reset. The ultimate parent account for any entity will have to be authorized by a recognized audit service or services that signs off on its real world identity and its electronic capability to join the community.

Preventing subversion of the DLT

Previous implementations of blockchain technology have been plagued by conflicts that lead to 'forks' in the blockchain where different members of the community try and subvert or change the original rules of operation without the agreement of all parties involved. These forks can be forced into existence when the governance model is not strong. The pharma DLT will require *"every transaction to include the hash of a recent block header. This hash serves two purposes:*

- *prevents a replay of a transaction on forks that do not include the referenced block; and*
- *signals the network that a particular user and their stake are on a specific fork.*

Over time all users end up directly confirming the blockchain which makes it difficult to forge counterfeit chains as the counterfeit would not be able to migrate transactions from the legitimate chain."[5]

Temporary Account suspension

A policing service will be used to automatically suspend suspected rogue nodes. As a private permissioned fork potential for focused denial of service attacks is already considerably reduced (as an identity would need to be stolen to access the community) but both blunt and focused attacks can be monitored for and the policing service can have the authority to temporarily freeze out a node.

Revocation of community privileges

The community can then vote to keep or revoke that node once the cause of the issue is identified

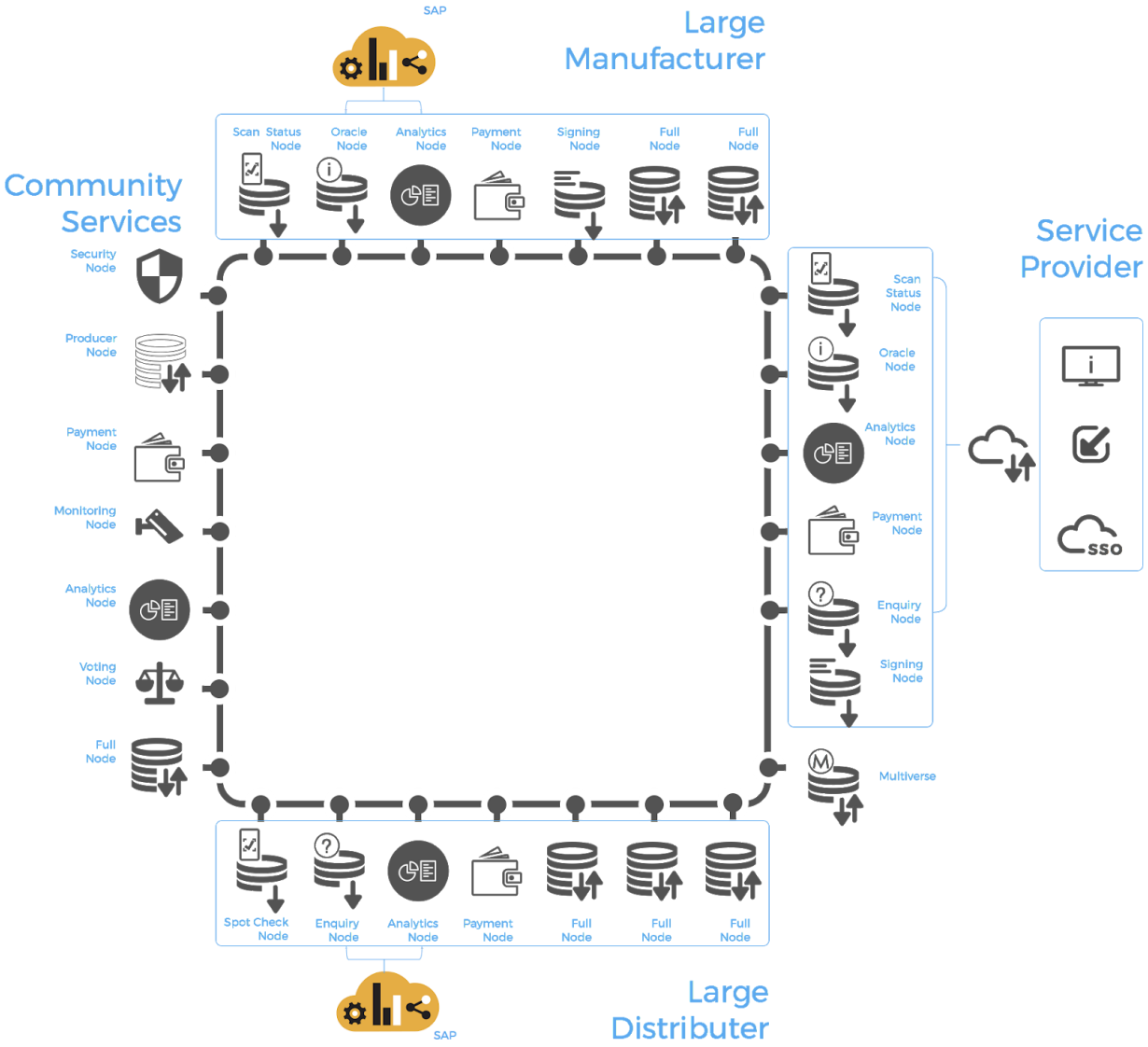
Debundled Node Architecture

The structure of a DLT allows and encourages discreet services to be maintained. This debundling increases distribution and resilience and allows participants to build out only the infrastructure they need. Each node type stays as simple as possible to allow fast implementation. The isolation of services means that upgrade

[5] Source EOS.IO White Paper June 2017

testing costs are kept to a minimum.

Diagram 1: Pharma DLT nodes



Community nodes needed

To operate, the community needs some shared services. Any member of the community can price and then provide shared services. The governance model allows the voting in and out of community service providers as long as an alternative provider is available.

Multiverse Node

Connects, provides responses and bills to alternative DLT providers. Connects, provides responses and bills to network enquiries.

>21 Producer Nodes

Produces the blocks for the DLT and stores a full copy of the ledger. There must be a minimum of 21 producer nodes available for the DLT to operate. They should be geographically distributed to provide platform resilience. Producers advertise their availability, capabilities and added value in order to solicit votes from the community so they can gain the rewards of producing blocks.

Monitoring and Security Node

Manages membership - prevents fake nodes from joining the community by managing authorization to participate

Policing Node

Monitors and temporarily freezes out nodes that are not conforming to community rules

Governance Node

Receives information from voting parties and reports results

Manufacturer nodes needed

Manufacturers can run their own nodes, use a service provider to represent them that runs those nodes on their behalf or join shared services on a cloud in order to keep costs down.

Oracle Node(s)

Protects manufacturer's proprietary data. Interfaces with, or stores a copy of all product data within the manufacturers domain. Responds to encrypted requests for information regarding its products. Signs contracts on behalf of that data.

Signing Node(s)

Signs and keeps a copy of all signed transactions by this counterparty

Payment Node

Manages subscriptions and contract payments. Receives community

payments for services provided by this entity

Scanning Interface Node (Optional)

Allows manufacturer systems or smartphones to check the status of products

Full node(s) (Optional)

Keeps a copy of the entire immutable ledger

Producer Node(s) (Optional)

Produces blocks. Receives income for doing so. Producers solicit votes in order to have the honor of producing blocks. 21 of them get to produce in a block cycle. The top 20 are cycled through at random and then one from the rest of the pool of possible producers is chosen.

Analytics Node

Allows users to check state of their product on an aggregate or discrete level by interfacing with both full nodes and signing nodes

Distributor nodes needed

Distributors can run their own nodes, use a service provider to represent them that runs those nodes on their behalf or join shared services on a cloud in order to keep costs down

Enquiry Node(s

Initiates an product enquiry and manages contract transactions

Signing Node(s)

Signs and keeps a copy of all signed transactions by this counterparty

Payment Node

Manages subscriptions and contract payments.

Scanning Interface Node

Allows distributer systems or smartphones to send enquiries on and check the status of products

DLT that can adapt to industry needs	By utilizing debundled services as nodes, the DLT for pharma will take maximum advantage of decentralization. Services can be isolated for replacement, upgrade, and testing. Service providers can be replaced and monopolistic behaviour avoided. By using contracts that allow fixed and consideration based pricing, new financial structures and T+0 invoicing become possible. Most importantly, the community comes with built-in governance, allowing these modifications to be made in a controlled manner and engendering a positive community of increased inventory control, regulatory compliance, and low transaction costs while keeping down the overall cost of adopting new functionality and improvements across the community.

Glossary of Terms

DLT	Distributed Ledger Technology - A coverall term for any community of services and users that requires no centralized control or authority to operate.
DSCSA	"The Drug Quality and Security Act (DQSA), was enacted by Congress on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. This will enhance the FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The system will also improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers."[6]
Community	All parties who currently or may in the future gain from or need to comply with reporting of unique identification of pharmaceuticals
Fork	A fork in a Distributed ledger is when records on some full nodes do not match the records of other full nodes and community users split

6 https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/

	the community in order to participate in their chosen version of the immutable ledger.
Hash	
Private Fork of a Public Chain	A private fork of a public chain is created when a part of the community chooses, on purpose, to provide all the services needed to run their own DLT and allow only permissioned parties to join them in their endeavour. Creation of a fork allows you to manage your own governance.
Governance	A broad term that denotes how a DLT manages itself. Some actions may be taken automatically by the nodes within the DLT and some may require input from the owners of the nodes.
HDA	Healthcare Distributors Association - a industry group that brings community members together to address community issues including compliance to FDA regulations
Nodes	The things that connect together to provide the services needed by the community and used by members of the community to access the community are called Nodes.
Smart Contracts	Small pieces of executable code that run under certain conditions and are written onto a block within the blockchain
Verified Returns	A Pharma term for the 2% to 4% of the pharmaceuticals that are returned for resale by distributors.