This application has been tested and is best accessible with Android phones. For questions about using this app, please contact Hamza Haque, Grade 8-2 (PACE program), Acadia Junior High.

MedSafe

Counterfeit Medicine Detection

Detect Counterfeit Medicine in the Pharmaceutical Supply Chain Using Blockchain Technology

Science Fair Project Report and Technical Design

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1. Abstract

Digital advances have enabled businesses and industries to streamline a plethora of interactions between customers and value chain partners. Currently it takes too long and is extremely hard to isolate the source contributing towards the counterfeit medicine that is causing harm. The objective of the project is to minimize the penetration of counterfeit medicine in the pharmaceutical supply chain and check the authenticity of the medicine using blockchain technology. The work on the blockchain solution is to see whether this emerging technological concept of distributed ledger is capable of being a reality or not for the pharma industry.

According to World Health Organization (WHO), billions of dollars (USD) worth of counterfeit medicines enter the market globally. Use of these fake medicines is a public health concern and results of millions of people dying around the world. In only two countries in Africa, 250,000 children died from taking fake medicine of malaria. Counterfeit medicines are a global problem and a global threat. The scope of this illegal trade is broad and complex, includes products spanning lifesaving treatments, involves multiple actors and enabling stakeholders[1], and impacts global populations from the poorest to the wealthiest[2].

This project uses emerging technology (blockchain) to counter penetration of fake medicines in the pharmaceutical supply chain, increase the transparency of medical management, and verify the medicines' authenticity via a Government issued Certificate of Authority (COA), once the medicines reach the end-user (patients). For this purpose, an application called MedSafe has been created. It that allows users to create a personalized patient profile and verify their medicine to check if it is safe or not. Blockchain technology enables the authentication of medicines using Hyperledger Fabric. This solution is useful for public safety to prevent non-standardized and fake medicines entering the marketplace.

Counterfeit medications are detrimental to a patient's health status. The use of fake and/or substandard drugs may result in adverse side effects, treatment failure, resistance, toxicity, and even death. It is important that pharmaceutical companies, healthcare professionals, government agencies, pharmacists, and patients be educated about counterfeit medications and the laws being enforced to prevent this crime. With increased awareness, taking advantage of emerging technologies, and the promotion of global health, the growing threat of counterfeit medications may begin to decline.

Technology can pave the way to stronger health systems and tackle serious problems facing human health worldwide. The strategic value and uniqueness of the solution shows tremendous potential impact to disrupt the supply chain industry.

[1] Law enforcement, regulatory agencies, manufactures, and customs officials etc.

[2] The American Journal of Tropical Medicine and Hygiene

2. Introduction

Counterfeit medicines are a global public health risk. A counterfeit medication or a fake drug is a medication or pharmaceutical product which is produced and sold with the intent to deceptively represent its origin, authenticity or effectiveness. The legitimate supply chains in developing and industrialised countries both are compromised.

In developed countries like Canada, we have 24/7 access to pharmacies (ex: Shoppers Drug Mart), we can also be sure that the medication/drugs are 100% safe and authorized by a government official. However, in underdeveloped and developing places in Africa and Asia, there are millions of people every year who get affected by a major disease. These people are prescribed medications but due to unaffordability, these people either go in debt or not buy the prescribed medications at all. This situation forces people to purchase from alternative sources selling unverified but cheap medicines. These poor consumers are led to believe that these cheap medications are 100% safe (due to brand name packaging) and authorized by government officials. Yet, little do the consumers know that these medicines are counterfeit and are made of indigestible material (ex: mud, dirt, bugs, etc.). Consumption of such fake medicines has caused people to have more illnesses and diseases than before. In fact, over 250,000 children died from taking counterfeit medicines in two countries in Africa alone that were supposedly meant to cure malaria[3]. Counterfeit medication is a worldwide problem.[4]

Some of the dangers and disadvantages of fake medicines in the marketplace are as follows:

- Damage to human health
  - Falsified and substandard drugs may contain toxic doses of dangerous ingredients and cause mass poisoning.
  - Poor-quality medicines compromise the treatment of chronic and infectious diseases, causing disease progression, drug resistance, and death.
- Loss of human lives
  - Counterfeit medicines have claimed millions of lives of the population globally.
- The Pharmaceutical Company's name (brand) suffers a loss in reputation and trust, due to damaged product. The reputation of the company is at stake.
- Government reputation suffers
  - The impression portrayed by the media (in some countries) is that the government is not doing anything to stop the penetration of fake medicines and neither is the government taking any steps to catch the culprits that manufacture counterfeit medicines in their countries. This gives a bad name to the government at the end of the day.
- Billions in losses is suffered by the businesses involved in the pharmaceutical supply chain.

[3] https://www.theguardian.com/science/2019/mar/11/fake-drugs-kill-more-than-250000-children-a-year-doctors-warn

[4] Assessment of counterfeit reports involving the legitimate supply chain using 2009–2011 data from the Pharmaceutical Security Institute Counterfeit Incident System (PSI CIS) database that uses both open and nonpublic data sources.

- Pharmaceutical companies need to have having stringent measures and proper controls to stop counterfeit medicines from entering their legitimate supply chains.

With a lot of illnesses and diseases rapidly growing in our modern-day society, it is important that genuine medications/drugs are always available for us at any time at an affordable cost. A pharmaceutical supply chain is the process through which medicines are manufactured and delivered to retailers (pharmacies, hospitals etc.). The medicines get manufactured in drug manufacturing sites; inspected and checked by government officials; are transferred to wholesale distributors; get stocked at retail places; hospitals and pharmacies buy and shelf the drugs; patient ultimately buys and takes the medicines.

The MedSafe app tracks, traces and authenticates medicines in every stage of their journey from the pharma company all the way to the patient. It leverages blockchain technology to introduce traceability and trackability into the pharmaceutical supply chain. This solution includes a mobile interface and the permissioned blockchain backend that gives each certified and authorized party in the network a way to initiate action, finish their transaction, track its progress, and verify that it was done correctly.

The Blockchain Proof of Concept (POC) application for validating real medicines from fake ones is going to determine whether the Blockchain project idea can be feasible in a real-world situation. The MedSafe drug detection application was created as a POC using blockchain Hyperledger Fabric. The MedSafe app verifies the stakeholder(s) of the pharmaceutical supply chain network, creates a login, authenticates the stakeholder(s) with unique identifier, provides role-based access, integrates with the supply chain and verifies the confirmation of the medicines as being genuine by a Certificate of Authority (COA) issued by the Government entity. The data is secure, private and transparent to relevant stakeholders with proper access controls.

The project helps to improve the visibility, traceability, and sustainability of a global supply chain for the pharmaceutical industry.

3. Project Purpose

The MedSafe application aims to decrease drug counterfeiting using Hyperledger Fabric (blockchain technology) for detecting and identifying counterfeit medicine in the pharmaceutical supply chain.[5]

The intent of this project is to 1) demystify the pharmaceutical supply chain, 2) demystify the problems of the pharmaceutical supply chain and how counterfeit medicine is affecting it, 3) propose a concept of using blockchain technology and integrating it with the pharmaceutical supply chain, 4) invent/make a prototype of a user-friendly app that uses blockchain technology. The user-friendly app called MedSafe will do the following[6]:

1. Allow patient to signup by creating a secure username and password
2. Allow patient to successfully login
3. Allow patient to create a personalized patient profile using Personal Health Information Number (PHIN)
4. Successfully store patient profile in a secure database
5. Allow patient to successfully edit/update their patient profile
6. Allow patient to successfully delete their patient profile
7. Allow patient to scan their pill QR code
8. Successfully display pill QR code information (see App)
9. Allow patient to copy and share pill QR code information (see App)
10. Allow patient to scan the Certificate of Authority (COA) QR code
11. Allow patient to view the COA – i.e. successfully display the COA information
12. Allow patient to sign out

[5] See What is Blockchain

[6] For a more detailed and in-depth explanation read the MedSafe App section of the report.

4. What is Pharmaceutical Supply Chain?

The current pharmaceutical supply chain in North America/Canada is the process through which medicines are delivered to patients. It starts with the medicine/drug manufacturer where the medicine is manufactured. The drug then goes through an extensive process of health and safety regulations, inspections and checking by government officials. If the government officials and the relevant Government Departments approve the medicine/drug, they issue a Certificate of Authority (COA) stating that this specific medicine/drug is 100% authorized and safe for consumer consumption. Once passed, the medicine is sold to a medicine/drug wholesale distributor. The distributor then sells the medicines/drugs in large quantities to various pharmacies and hospitals. The pharmacy then stores and shelves the medicines. Medicines that are over-the-counter are stored and are not shelved. The patient then either gets their specific medicines delivered through mail-order or goes and physically buys it.

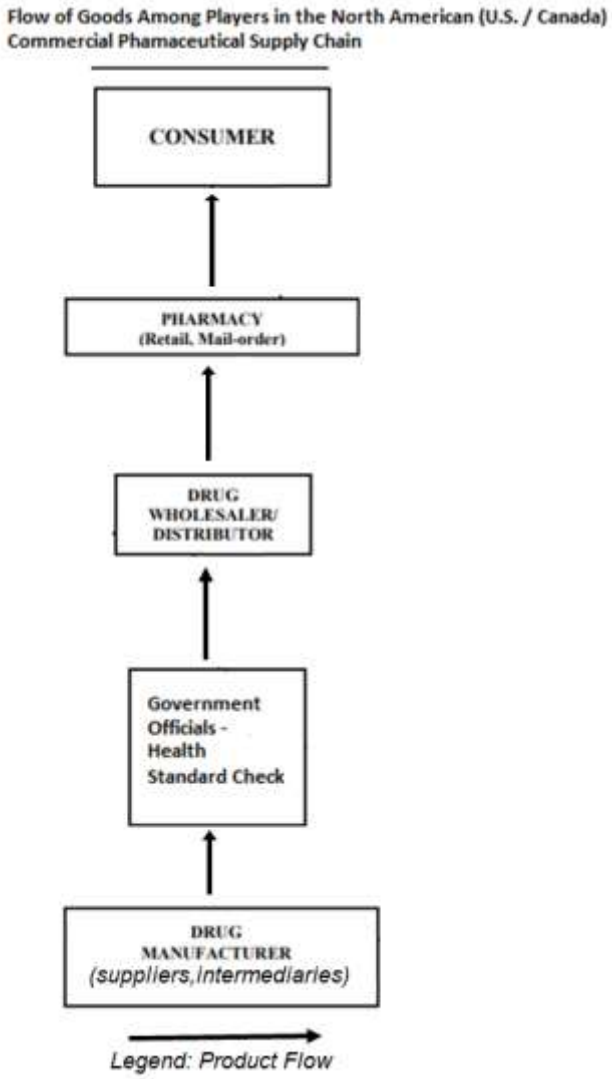

Figure 1: Pharmaceutical Supply Chain

4.1 Current Challenges/issues of Pharmaceutical supply chain

Like any other industry, the pharma industry too is susceptible to challenges and risks. One of the most complex and challenging problems faced because of the globalization of health-care delivery is securing the integrity and safety of the global medicines supply chain. Dangerous forms of pharmaceuticals are illegally sold by criminal elements and unlawful transnational organizations (online pharmacies) creating patient safety and public health dangers that weaken public and private investments in health care[7].

The solution to this growing problem includes both long-term and short-term options. These includes better visibility across the supply chain, and have incentives put in place with policy to enable companies to correct the issues with the drug supply chain. Several organizations have detailed increasing challenges to safeguarding the global medicine supply chain.

Some of the challenges faced by the pharma industry are as follows:

- **Global complexity leading to lack of transparency and trust in supply chain**
  - Deficiency in collaboration between different players globally; Integrity (counterfeit, theft); Requirements Guidelines (different regulations globally, different data requirements); Resources (inspections and reviews, training to strengthen expertise, lack of training); Fragmentation (minimum inventory, release testing); Implementation of Changes (review times, Government and bureaucratic delays); numerous different levels of policies, rules and regulations globally.

- **Supply Chain not in Sync**
  - Not all processes in the pharma supply chain are automated. This results in reduced anti-counterfeit mechanisms in place making the supply chain unsecure and vulnerable. The Health Information Systems need to mature globally.

- **Weak or inconsistent legal frameworks**
  - The lack of regulations to address quality and sales, often carried out online or in informal locations, add to the problem, according to the United Nations (UN). Government should

[7] https://mosaicscience.com/story/fake-drugs-global-antibiotics-amr-counterfeit-meds/
In late 2012, 60 people died in two cities in Pakistan after drinking cough syrup. Syrups from two separate manufacturers were involved. It was found that both were using an active ingredient – dextromethorphan, a synthetic morphine-like compound – imported from the same manufacturer in India. Indian drug authorities put a halt to production while they investigated.

Tests in Pakistan revealed that the medicines seemed to contain the correct amount of active ingredient. But further tests revealed something that was not supposed to be there. Levomethorphan, a chemical five times stronger than morphine, was the contaminant that had caused the deaths.

develop a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities and drug production.

- **Organized criminal groups engaged**
  - These groups are involved in falsified medical product-related crime using the same routes and techniques employed in the trafficking in other illicit commodities. In so doing, they exploit gaps and discrepancies in supply chain, legislations and criminal justice systems. In many countries, criminal groups use new technologies and platforms to traffic in falsified medical products and avoid detection by law enforcement authorities.

- **Easy penetration due lack of Anticounterfeiting Technologies**
  - The pharmaceutical supply chain is vulnerable to risks. The infiltration of counterfeit medications and medical products is one of the major challenges the pharma industry faces. (See relevant section in the document).[8]

- **Inconsistent legal frameworks globally**
  - Initiatives need to be undertaken in cooperation among different countries and government agencies to combat falsified medical-related products reaching vulnerable consumers.

- **Self-Service Verification and Lack of Transparency on the Consumer's end**
  - Currently patients cannot verify through self-service way if the medications prescribed to them is genuine and safe for consumption. There is no option available for patients to confirm and guarantee the medicines have been examined and authorized by Government Departments.

- **Illegal supply chains**
  - Transnational smuggling is a critical component in illegal supply chains and is responsible for the movement of counterfeit medicines from source origin to the markets where they are consumed. Counterfeits are increasing in the virtual marketplace. Examples of illegal parallel supply chain (selling on the streets, fraud online pharmacies, smuggling through customs etc.).

- **Product damage and Company's reputation (brand name repute)**[9]
  - In 2009, Johnson & Johnson made several recalls of their popular over-the-counter pain reliever Tylenol after a musty odor was reported by consumers. The company was continually forced to make larger recalls over the next couple of years, with the final one in 2011. The origin of the musty smell consumers had been reporting was finally traced back to

[8] https://igps.net/blog/2018/05/24/the-top-5-pharma-supply-chain-challenges-in-2018/

contamination of the product from shipment on wood pallets treated with a fungicide that had decayed into 2,4,6-tribromoanisole, causing the odor as well as non-serious gastrointestinal distress for customers who consumed the tainted medicine. Irreparable harm was done to the Tylenol brand and parent company Johnson & Johnson's reputation, not only because of the recall, but also because of how long it took to discover the cause and fix it.

- **Human Resource Dependency**
  - Even though the pharmaceutical supply chain and logistics are being automated, there is still dependency on human intervention in the current pharmaceutical supply chain, such as logistics, checking of ingredients for drug making, manufacturing, testing, packaging, labelling, quality inspection, delivery etc. Human error is inevitable.

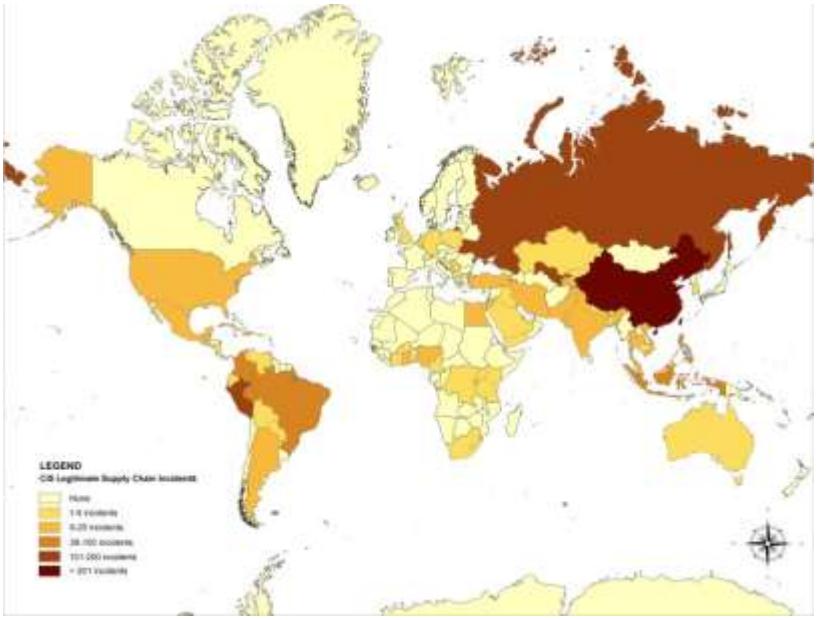

Figure 2: Global map of Counterfeit Incident System (CIS) Counterfeit Incidents by country.

4.1.1 Penetration of Counterfeit Medicine in Pharmaceutical Supply Chain

Counterfeit medicines are one of the major causes of death in underdeveloped countries. In underdeveloped countries, people often buy the counterfeit medicines instead of the real and safe medicines primarily due to lack of knowledge and economic difficulties. There are three main ways through which counterfeit medicines enters the market:

- On the street
- Via internet (online)
- In the legitimate supply chain

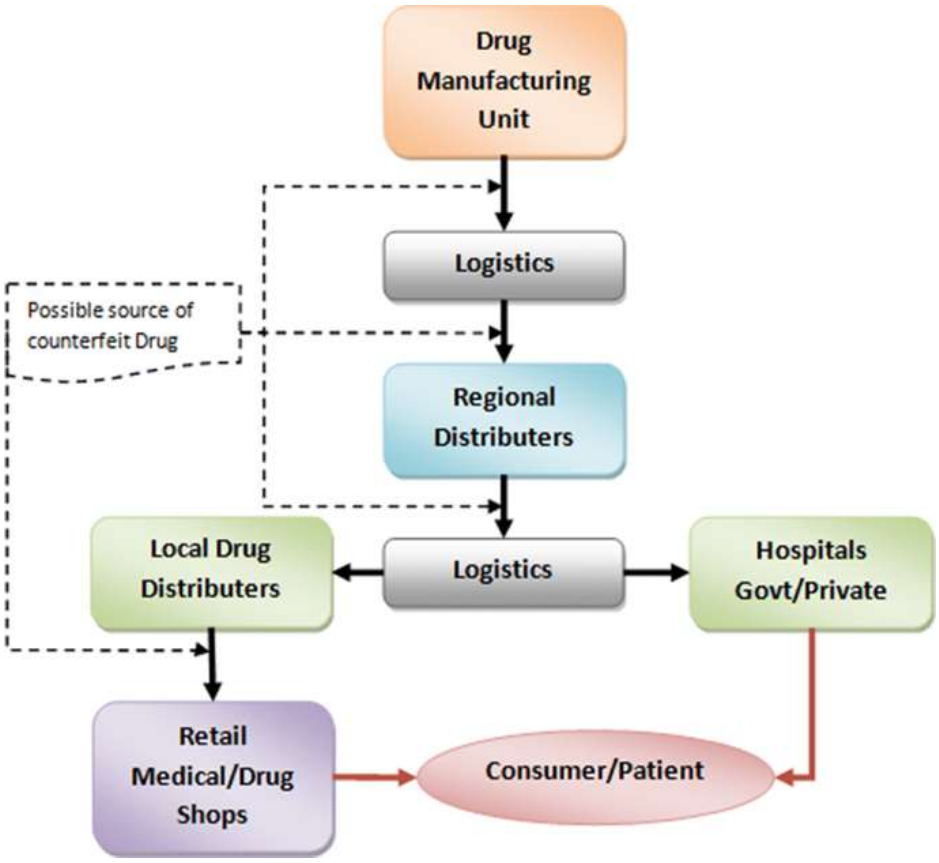

Figure 3: Counterfeit Medicine Penetration Points[10]

Legitimate Supply Chain

A total of 127 (64.8%) of a total of 196 countries had no legitimate supply chain. Improvements in surveillance, including detection of security breaches, data collection, analysis, and dissemination are urgently needed to address public health needs to combat the global counterfeit medicines trade.[11]

The legitimate pharmaceutical supply chain has many different stages through which counterfeit medicines can enter, starting with the collection of raw materials (ingredients) and manufacturing of the medicines/drugs. Other stages include storage, transportation, and distribution. Once a counterfeit medicine has infiltrated the pharmaceutical supply chain it is extremely hard to identify when and where the penetration occurred. This is because about 90% of pharmaceuticals/medicines go through so many

[10] https://link.springer.com/article/10.1007/s11277-020-07041-7

How many counterfeit drugs are there? https://www.bbc.com/news/world-africa-51122898

Globally, the trade in counterfeit pharmaceuticals is worth up to $200bn (£150bn) annually, with Africa among the regions most affected, according to industry estimates. The World Health Organization (WHO) says 42% of all fake medicines reported to them between 2013 and 2017 were from Africa. The European region and the Americas (North and South) accounted for 21% each.

[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4455087/

stakeholders in a supply chain (ex: a medicine can go through 1 manufacturer, 3 or 4 distributors, 2 pharmacies and many other unknown stakeholders). In one case, counterfeit Epogen (medical product) which was purchased from a pharmacy had at least 12-13 chains of owners in the pharmaceutical supply chain just for this counterfeit Epogan! This counterfeit caused tremendous health issues to a young patient who had undergone a liver transplant in the U.S. In addition to the manufacturer and the major distributor, this drug was handled and managed by three (3) wholesale distributors, two (2) pharmacies, four (4) unlicensed go-betweens and one (1) suspected counterfeiter. This tragic incident is only one of millions of incidents related to counterfeit medicine that have caused many health issues and loss of lives for the patients. The scope of this illegal trade is broad and complex, includes products spanning lifesaving treatments, involves multiple actors and enabling stakeholders[12], and impacts global populations from the poorest to the wealthiest[13].

4.2 Integrating Blockchain into Pharmaceutical Supply Chain

Blockchain technology is a secured and distributed ledger that requires all of its users to make a decision on a certain piece of data. (If approved) the data then gets stored in the blockchain as a block. The block cannot be deleted nor changed. If blockchain is integrated with the pharmaceutical supply chain then fraudulent drug traffickers can easily be identified because every block in the blockchain network is timestamped and immutable. Another benefit is that the medicine's data is secure and the supply chain is transparent. Since the supply chain is transparent, this enables patient to get a full in-depth review of who are the individual players involved in the supply chain (such as manufacturing, distributing, etc.) of their pill. The patient will also be able to see a Government issued Certificate of Authority (COA) stating that the medicine they are taking is verified, genuine and safe for consumption.

Some of the advantages of using blockchain technology in the pharmaceutical supply chain infrastructure are as follows:

- **End-to-end traceability of health products:**
  A pharmaceutical supply chain integrated with blockchain technology will enable streamlined visibility of movement and stakeholders through which medicines transit in the supply chain. This improved traceability facilitates the optimization of flows of goods/materials, ensures an efficient stock management and inventory system which in turn improves the traceability of medicines in the supply chain.

- **Reduced losses related to counterfeiting**:
  A blockchain network allows patients to have a clear visualization of their medicine's journey from manufacturer to pharmacy with digitalized transactions. Thus, it is possible to examine any weak

[12] Law enforcement, regulatory agencies, manufactures, and customs officials etc.
[13] The American Journal of Tropical Medicine and Hygiene

links in the pharmaceutical supply chain to reduce the chances of fraud and the costs related with it.

- **Transparency to enhance accountability**:
  In the blockchain network, every stage of the medicine throughout the pharmaceutical supply chain can be traced and tracked. This also opens the possibility of tracing the stakeholders (manufacturer, pharmacy, distributor, etc.) involved in the pharmaceutical supply chain. If a problem were to occur (e.g. malicious node) then it is possible to check the supply chain in the blockchain network and identify which stakeholder caused the problem.

- **Efficient recall management:**
  Using blockchain in the pharmaceutical supply chain enables quick identification of the exact locations of the medicines. This improves the efficiency of an event where the medicines have to be called back to the last stakeholder for a particular reason while maintaining the patient's safety and health.

5. What is Blockchain?

Blockchain is a new rapidly growing technology that is expected to change the security of digital transfers. Blockchain is a secured, distributed and decentralized public ledger. In simpler words, it is a chain of blocks that stores information in many different computers at once across the internet. This makes it hard for anyone to break into a single computer or steal the data. Blockchain technology allows users to access the same information at the same time. All information is accessible to all participants at the same time. No one person can control the data. Blockchain records various kinds of information. It can record money, identities, music, or even agreements between people. The technology removes distrust as all the information that is meant to be there is captured. If someone tries to change data, it spoils the code, and all users will know about it. That is what makes blockchain accurate, reliable, and convenient.

Blockchain was first developed as a technique by a group of researchers in 1991. It was originally meant to act like a notary (meaning that digital documents were timestamped so it would not be possible to backdate and tamper them). Yet, Blockchain was very uncommon and was kept under the radar. But, in 2009 Satoshi Nakamoto created the digital cryptocurrency (digital currency) called Bitcoin. Satoshi Nakamoto integrated blockchain technology and Bitcoin together making blockchain a popular new technology. Blockchain makes it possible for 2 or more entities (e.g. people, businesses or computers) that may or may not know each other to exchange value in digital environments without having an intermediary. Blockchain is a distributed database that everyone can get a copy of. Every person with a copy can add new records to this database but cannot change any record that's already in there. This property makes blockchain great to record data in a transparent and secure way because everyone gets to see what's in it.

The blockchain used in this project is called Hyperledger Fabric. This private blockchain network is used to target counterfeit medicines by timestamping every drug manufactured. This makes each and every drug traceable with its origins and its pharmaceutical supply chain details (who is the manufacturer, who is the distributor, etc.).

5.1 How Blockchain Works

A Peer-to-Peer (P2P) network is where all the nodes (user/stakeholder) control the blockchain network together, and vote on storing new blocks in a blockchain, without a third-party. Each block is identified using a hash. A hash is a unique component of a block that can be compared to a fingerprint. Every block's hash is calculated and generated according to the previous block's hash. This is what makes the chain of blocks. Consensus algorithms (such as Proof-of-Work, Proof-of-Stake, etc.) and anti-tampering mechanisms are being tested for blockchain validation.

After a block has been added to the end of the blockchain, it is very difficult to go back and alter the contents of the block. This is because each block contains its own hash, along with the hash of the block before it. If the block information is edited in any way, the hash code changes as well. That is if block #2 were tampered, then the hash of block #2 would get changed and in turn would cause block #3 and all

the following blocks to become invalid since they are not storing a valid hash of the previous block. This ensures that changing the block will make all following blocks invalid. That is why hash is important to security. Once a block is added to the blockchain it becomes very difficult to edit and impossible to delete. Blockchains have an element called Smart Contracts. A smart contract is a protocol that executes when predetermined terms and conditions are met (ex: when Person A receives medicine, smart contract releases payment to Person B). This eliminates the need of a third-party organization.

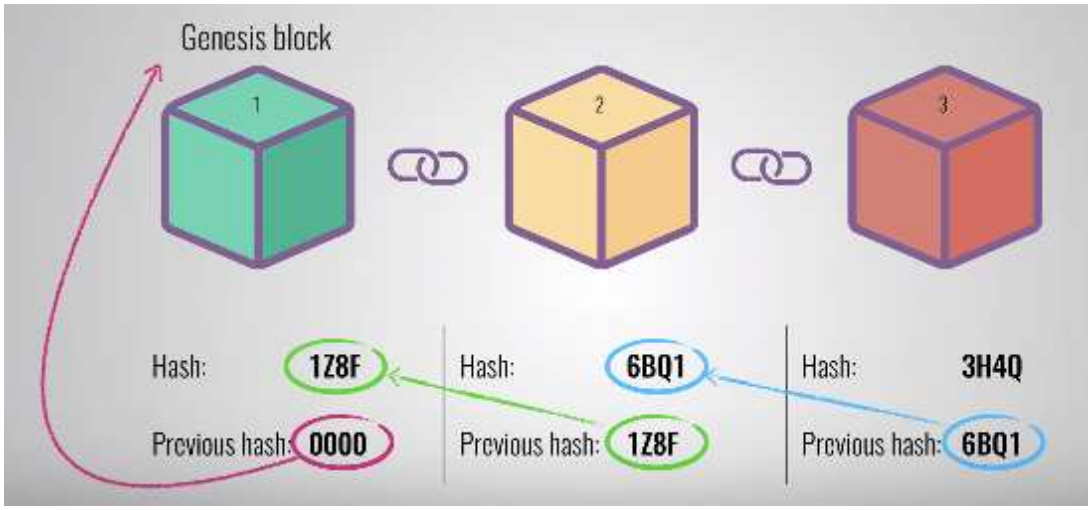

Figure 4: Blockchain Hash

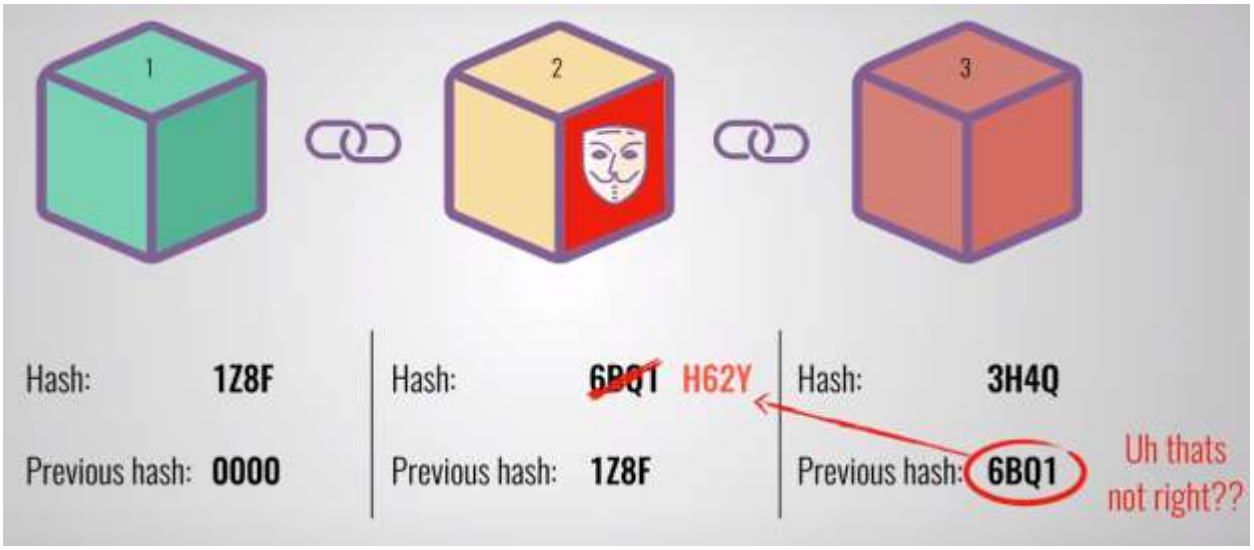

Figure 5: Blockchain hash changed

6. Proposed Solution

The pharmaceutical supply chain is a fragmented system that will benefit from emerging technologies for enhanced efficiencies and improvements. This project has created a solution by integrating blockchain technology into the pharmaceutical supply chain. It has also created an application called MedSafe to provide the consumer a user-friendly mobile interface (UI). This solution is divided into four steps through which the consumer (patient) can receive, verify and consume safe medicines.

Step 1: Manufacturer manufactures the drugs and adds QR code to it

The first step in this new pharmaceutical supply chain involves the manufacturer. The manufacturer will produce the medicines and adds a QR code to it. The QR code contains essential and important information like timestamp, medicine name and details, location of manufacturing and expiry date. The manufacturer, making it possible for the other stakeholders to trace the medicines' pharmaceutical supply chain transparently, adds the information on to the blockchain. Once the information is stored in the blockchain a hash is produced which can be used for tracking back the medicine and transactions. Before the manufacturer can send the medicines to the distributors, the medicine has to be checked by government officials. Once the medicines are checked, the government issues a Certificate of Authority (COA) stating that the medicines are 100% safe, validated and authenticated. The manufacturer then sends the medicines to the distributor; all the stakeholders will be able to track the medicines in the blockchain using real-time location systems (RTLS). Once the distributor has received the medicines, the payment/funds from the distributor to the manufacturer will be released through smart contracts (an algorithm and secure way funds/payments or assets are sent and received – this ends the need for a third-party to hold and release the funds or assets between two parties in a transaction, aka escrow[14]) in the blockchain network.

Step 2: Distributors send the medicines to pharmacies/hospitals

Once the distributors have received the medicines from the manufacturer, they can verify the origin and the authenticity of the medicine using the hash stored in the blockchain network. The distributor will trace back the information added by the manufacturers as well as if it passed all the required quality check or not. The distributor will do this validating step to ensure that they are not in the possession of counterfeit medicine. Because if they approve and distribute the medicines without realizing that it might be counterfeit then they can face serious charges and allegations. Once the medicines are validated and checked, the distributors validate the authenticity of the received medicines and sign the transaction digitally. This is then added to the blockchain network. Once the blockchain has stored the signed transaction, a smart contract is triggered which sends the medicines to various hospitals and pharmacies.

[14] An escrow is a financial arrangement where a third party holds and regulates payment of the funds required for two parties involved in a given transaction.

Step 3: Pharmacies receive the medicines. validate its source and ensure the medicines are genuine

The medicines are now in the possession of the pharmacy. The pharmacists also verify the origin and the authenticity of the medicine by using the hash in the blockchain network. The pharmacists, to avoid facing serious charges and allegations on having the possession of counterfeit medicine, will also do the same verification steps taken by the distributor. If the pharmacists find that the medicines they received are from an illegal distributor who is selling counterfeit drugs the transaction will be considered invalid and the blockchain network will automatically expel the distributor. If the medicines are valid, the pharmacists approve the received medicines and finalize the transaction between them and the distributor. The transaction is then stored in the blockchain ensuring a legal deal.

Step 4: Patients buy the medicines and scan the QR code to trace back its source

The patient can be assured if the medicine they are buying is safe to take or not. They can do this by downloading the MedSafe app and creating an account. In the account, they can create a personalized patient profile. They can also use a built-in QR code scanner in the app that lets the patient scan their QR code, which is attached to the pill's packaging. Once the QR code is scanned, the app displays the pill's information from the blockchain. This allows the patient to see the pill's information in a user-friendly platform. The patient can also scan another QR code, which is the COA of the pill, issued by the government. Once scanned, the app retrieves the pdf version of the COA and requests the user for permission to download it. When the COA is downloaded, the patient is able to look at the COA issued by the government. The COA helps the user verify that the medicine they are consuming is safe.

7. MedSafe App Development – Technological Innovation

7.1 Logo

Figure 6: MedSafe App logo

7.2 What the App does?

This application is called MedSafe. It is a mobile app to ensure the patient is receiving certified medicine verified by the relevant Government Agency(ies) and issued an appropriate Certificate of Authenticity (COA).

Using the mobile application all the stakeholders (such as government inspection agency, pharmaceutical industry, whole sellers, distributors, retailers, consumers) will scan the label of drugs, showing all the history information from manufacturers to the retailers from the app. The ability to track and trace the non-standardized or fake medicine for the public safety, customers will know the history and originality of their purchased medicine. Manufacturers will benefit the elimination of their brand fake medicine producers. Ultimately, the project aims to save thousands of lives due to fake medicine globally.

7.3 Why the App was Made?

This app was made because of the rapidly booming industry of counterfeit medicine. Counterfeit medicine has been such a problem that the World Health Organization (WHO) has named it a major world issue. Counterfeit medicine is made in secret and undisclosed factories. These fake drugs then are packaged under authorized brand names and sold in underdeveloped countries at cheap prices. These reduced prices make the patients buy the counterfeit medicine instead of the authorized and true medicines. The patient then takes a regular intake of the counterfeit medicine thinking that their illness will improve. However, after some time, the patient gets even worse and develop severe health issues sometimes even leading to death. In fact, in Africa over 250,000 children died because of counterfeit medicine for malaria. Therefore, the MedSafe app detects counterfeit medicine using QR codes and blockchain technology to ensure safe availability of verified medicines for the people.

7.4 How the App was made

Step 1: An overview of what and how the app would look like was created.

- How the final product will look like.
- A high-level design and functionality list was created
- A technology architecture diagram showing an overview of an entire system, identifying the main components that would be developed for the product and their interfaces was created

Step 2: The blockchain network was created as a back-end for the app, using Hyperledger Fabric and IBM Blockchain Platform.
Step 3: API/REST API (REpresentational Application Program Interface) created using Android Studio's built in features.
Step 4: Android application developed to provide a user-friendly interface.

- User authentication created
- Using REST API's and secure database, app is able to make sure usernames stay unique

Step 5: Two databases created using Firebase.

- One database created to store patient's login credentials
- Other database created to store patient profile, stored using PHIN

Step 6: Tested application

- App tested according to testing criteria

7.5 App Functionality

The functionality of the app requires the user/patient to sign up with a username and password. Once the user account is created, the login credentials are stored in a secure Firebase Database. The user can now login using their login credentials. Once the user/patient has successfully logged in, they can create a patient profile with their unique PHIN.

The patient profile includes the following:

1. First Name
2. Last Name
3. Telephone
4. Email
5. Date of Birth
6. Address
7. Family Physician
8. Gender
9. Comments
10. PHIN Number

The user/patient fills out the patient profile and saves the information. The data is then stored in another Firebase Database. Once the data is stored in the database, the app retrieves the data stored and displays the information on the patient/user's screen. The patient/user can edit and modify their patient profile whenever needed. The patient/user can also delete their patient profile whenever they need to. This action causes the database to delete the data ensuring a high-level of security and privacy. The app also allows the patient/user to scan the QR code that displays a digital prescription of their medicine ensuring that it is safe and not counterfeit. The app also displays the route of the medicine from the blockchain technology. Meaning that the patient/user gets to see where the medicine has been manufactured, distributed, etc. and who manufactured the medicine, distributed, etc.

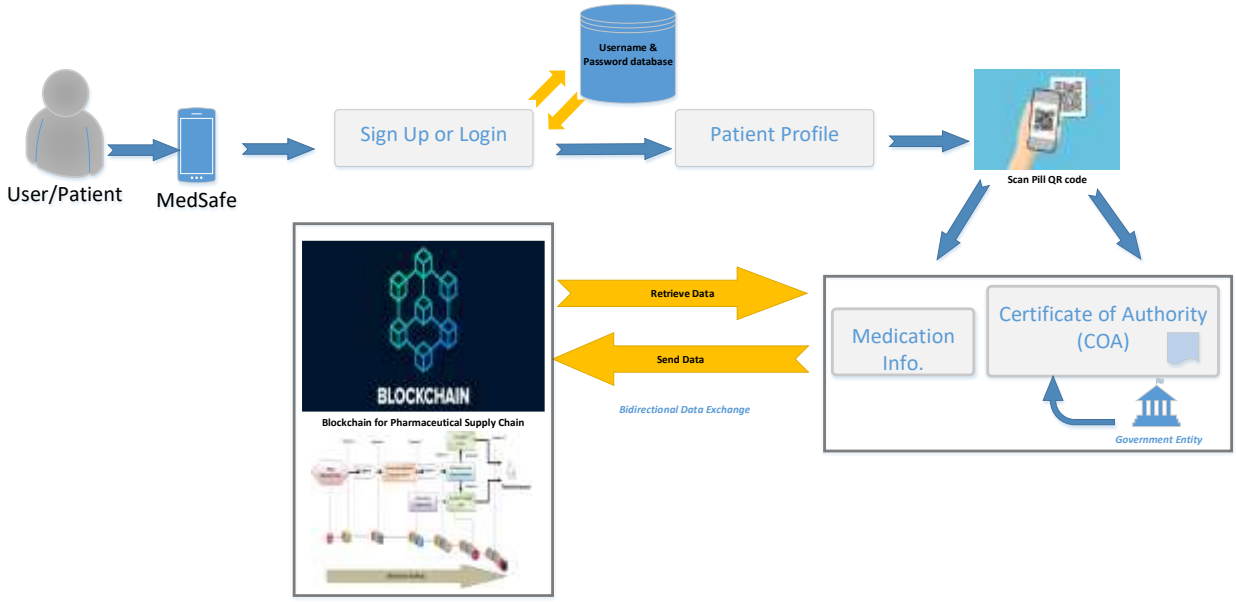

Figure 7: App Overview

7.5.1 App – SignUp / Login Page

Figure 8: MedSafe App - first screen

Figure 9: App SignUp page

Figure 10: App Login page

Figure 11: MedSafe App - Patient Profile

Figure 12: Pill Profile - 1st screen

Figure 13: QR scanner

Figure 14: Pill Profile - QR info

7.6 Output - QR scanner and QR codes

Sample Data

Sample Data

Sample Data

Sample Data

Sample Data

Sample Data

8. Application Testing - (MedSafe)

An application-testing checklist was created and the MedSafe app was tested against it as follows:

No.	Criteria	Result
Back – End (Blockchain and Database)		
1.	Add A Stakeholder	✓
2.	Enter Data	✓
3.	Store Data	✓
4.	Send Asset Transactions With Smart Contracts	✓
5.	Synchronization between the database and the values displayed in our client/web	✓
6.	Query results, views, stored procedures, etc.	✓
7.	Data manipulation (update, delete, insert etc.).	✓
8.	Validate the DB behavior in case of service failures (recovery).	✓
9.	Validate that DB tables are created with informative and reasonable names.	✓
10.	Validate the software security model (appropriate user roles, permissions etc.).	✓
11.	Validate restore and backup plans (business continuity).	✓
12.	Check that all data is logically organized in the relevant DB tables.	✓
13.	Check that each data item is located under the relevant column.	✓
Database and software integration		
1.	Validate that the user data is saved when the user “Apply” or “Submit” the changes.	✓
2.	Validate that the user receives the current result when pulling data.	✓
3.	Validate that the values displayed are based on the database data.	✓
4.	Correct invalid date format on date fields.	✓
User Interface		
1.	Check all UI elements for size, position, width, length, and acceptance of characters or numbers. For instance, user must be able to provide inputs to the input fields.	✓
2.	Check that the intended functionality of the application using the UI is executed properly	✓
3.	Check Error Messages are displayed correctly	✓

4.	Check for Clear demarcation of different sections on screen	✓
5.	Check Font used in an application is readable	✓
6.	Check the alignment of the text is proper	✓
7.	Check that the images have good clarity	✓
8.	Check that the images are properly aligned	✓
9.	Testing the alignment of the texts and other elements like icons, buttons, etc. are in proper place or not.	✓
10.	The user must not get frustrated while using the system interface.	✓
QR code and scanner testing		
1.	QR code has been tested for readability	✓
2.	QR scanner is easy to use	✓

Table 1: App Testing

9. Conclusion

The growing phenomenon of the falsification of medical products threatens the right to life. The manufacture and distribution of medicines is a global industry, tainted by fake and substandard products. Not only do these drugs not work as expected, but also some are even contributing to loss of human lives posing a risk to human health.

The globalization of the pharmaceutical supply chain has introduced new challenges, such as fighting the international criminal trade in fake medicines. As the manufacture, supply, and distribution of drugs becomes more complex, so does the need for innovative technology-based solutions to protect patients in North America, Canada, and globally. In some regions of the world, the trafficking of counterfeit medicines are crimes of opportunism, and in others, a part of a complex and organized global criminal enterprise[15].The trade in counterfeit goods is often perceived as a "soft" form of crime, but can have dangerous consequences for public health and safety. Fake medicines in particular pose a threat to public health, and their use can develop further complications in a patient's health (such as blindness), sometimes even resulting in death. To effectively address this challenge, it is important to combine law enforcement agencies, public health perspectives from both public and private resources, and technical innovation solution providers, because no single entity can accomplish this goal alone. Technology is a powerful enabler to tackle the threat of counterfeit medicines in legitimate pharmaceutical supply chain.

The MedSafe app was designed, created, tested (performance evaluation) successfully. The MedSafe app was able top achieve its goals of counterfeit medicine detection. The proposed system is a proof-of-concept (POC) application that tracks individual drug records and verifies their authenticity through integration with the blockchain platform based on Hyperledger Fabric. The potential future direction would be to deploy this POC in a real world environment. The scope of and results from the MedSafe Drug Detection App currently focused on the end user/consumer (patient). The testing of the app's functionality passed the required checklist and did not show any inaccuracies or delays. For further work on the project progresses (future steps – phase 2), additional stakeholders from the pharmaceutical supply chain will be included. The MedSafe app will be beneficial for improvements in identifying and tracking counterfeits as well as promoting global public health interventions and surveillance in this area. The MedSafe app can be leveraged as a possible foundational model for health technology for the development of a global counterfeit detection system that can be used for reporting cases of counterfeit, falsified and/or substandard medicines.

To eliminate fake medicines from the market, and save the thousands of lives, this project used emerging blockchain technology solution to combat this challenge. This approach increased the safety and transparency of the medicine making industry, tracking the pharmaceutical supply chain, improving

[15] UN Office of Drugs and Crime Transnational Organized Crime in East Asia and the Pacific: A Threat Assessment. 2013. http://www.unodc.org/toc/en/reports/TOCTA-EA-Pacific.html Available at. Accessed Feb 11, 2020.

information sharing and data collection, and designed to overcome existing barriers of adoption and implementation in North America, Canada and globally. Investment in this new emerging blockchain technology is essential to ensure the future security and integrity of the global drug supply chain.

10. Application / Next Steps – Future Phases

Blockchain is a revolutionary technology that has great potential for various industries like financials, insurance, real estate, healthcare etc. Blockchain offers greater transparency, increased efficiency, better security, improved traceability, enhanced security and auditability capabilities. Major industries (financial sector, stock markets) and organizations (e.g. banks) have already invested millions to develop platforms to clear transactions using blockchain systems. Blockchain is so important because it opens up new possibilities, with numerous applications and a high disruption potential.

This project will expand in future phases promoting best practices with additional measures designed to detect counterfeit medications penetrating the legitimate pharmaceutical supply chain will be developed. Some of the features such as universal patient profile, collaboration of stakeholders for proper identity management and accessibility, enhanced level of security, better drug traceability enabling easy to track transactions in real-time, utilizing 3-D printing of pills with embedded edible QR codes, and improved speed and efficiency have been identified. Future phases of the drug detection system shall provide functionality to collect, store, manage and transmit patient's electronic medical records (EMR), enforce policy decisions and provide reporting capabilities as well. The system is expected to support improvements in the patient outcomes, reduction in operational cost, improve utilization of resources, and improve the timeliness of decisions.

Technology can pave the way to stronger health systems and tackle serious problems facing human health worldwide. The strategic value and uniqueness of the solution shows tremendous potential impact to disrupt the supply chain industry.

Appendix A: Certificate of Authority (COA) - #1

Health Canada Santé Canada

Compliance and Enforcement: Drug and Health Products

Certificate of Authority (COA)

Pharmaceutical Drug

No. of certificate: 72901	Exporting (certifying country): United States of America
	Importing (requesting country): Canada
1. Name and dosage form of the product: Acetaminophen – 1 pill = 500 mg	1.1. Active ingredient(s) and amount(s) per unit dose: Ingredients shown on attached document, amount depending on patient 1.2. Is this product licensed to be placed on the market for use in the exporting country? (yes/no) 1.3 Is this product actually on the market in the exporting country?: Yes
	If the answer to 1.2. is yes, continue with section 2A and omit section 2B. ~~If the answer to 1.2 is no, omit section 2A and continue with section 2B:~~
Section 2	2.A.1. Date of issue: 1955 (original) 2.A.2. Product licence holder (name and address): McNeil Consumer Healthcare - 7050 Camp Hill Rd, Fort Washington, PA 19034, United States 2.A.3. Status of product licence holder: Active 2.A.4. Is a summary basis for approval appended? (yes/no) 2.A.5. Is the attached, officially approved product information complete and consonant with the licence? (yes/no/not provided) ~~2.A.6. Applicant for certificate, if different from licence holder (name and address):~~ ~~2.B.1. Applicant for certificate (name and address):~~ ~~2.B.2. Status of applicant: (Key in appropriate category as defined in footnote 8)~~ ~~2.B.2.1. For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:~~ ~~2.B.3. Why is marketing authorization lacking? (not required/not requested/under consideration/refused)~~ ~~2.B.4. Remarks:~~
Section 3	3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (yes/no/not applicable) If not or not applicable, proceed to question 4. 3.1. Periodicity of routine inspections (years): 6 months 3.2. Has the manufacture of this type of dosage form been inspected? (yes/no) 3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization? (yes/no/not applicable)
Section 4	4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product: (yes/no) If no, explain: Address of certifying authority: 70 Colombine Driveway, Ottawa, ON K1A 0K9 Telephone: (613) 957-2991 | Fax: 613-941-5366

Appendix B: Certificate of Authority (COA) - #2

Health Canada Santé Canada

Compliance and Enforcement: Drug and Health Products

Certificate of Authority (COA)

Pharmaceutical Drug

No. of certificate: 80245	Exporting (certifying country): United States of America
	Importing (requesting country): Canada
1. Name and dosage form of the product: Atorvastin Calcium – 1 pill = 10 mg	**1.1. Active ingredient(s) and amount(s) per unit dose: Ingredients shown on attached document, amount depending on patient** **1.2. Is this product licensed to be placed on the market for use in the exporting country? (yes/no)** **1.3 Is this product actually on the market in the exporting country?: Yes**
	If the answer to 1.2. is yes, continue with section 2A and omit section 2B. ~~**If the answer to 1.2 is no, omit section 2A and continue with section 2B:**~~
Section 2	2.A.1. Date of issue: 1994 (original) 2.A.2. Product licence holder (name and address): Pfizer - **235 E 42nd St, New York, NY 10017, United States** 2.A.3. Status of product licence holder: Active 2.A.4. Is a summary basis for approval appended? (yes/no) 2.A.5. Is the attached, officially approved product information complete and consonant with the licence? (yes/no/not provided) ~~**2.A.6. Applicant for certificate, if different from licence holder (name and address):**~~ ~~**2.B.1. Applicant for certificate (name and address):**~~ ~~**2.B.2. Status of applicant: (Key in appropriate category as defined in footnote 8)**~~ ~~**2.B.2.1. For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:**~~ ~~**2.B.3. Why is marketing authorization lacking? (not required/not requested/under consideration/refused)**~~ ~~**2.B.4. Remarks:**~~
Section 3	3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (yes/no/not applicable) If not or not applicable, proceed to question 4. ~~**3.1. Periodicity of routine inspections (years):**~~ ~~**3.2. Has the manufacture of this type of dosage form been inspected? (yes/no)**~~ ~~**3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization? (yes/no/not applicable)**~~
Section 4	4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? (yes/no) ~~**If no, explain:**~~ Address of certifying authority: 70 Colombine Driveway, Ottawa, ON K1A 0K9 Telephone: (613) 957-2991 | Fax: 613-941-5366

Appendix C: Certificate of Authority (COA) - #3

Health Canada Santé Canada

Compliance and Enforcement: Drug and Health Products

Certificate of Authority (COA)

Pharmaceutical Drug

No. of certificate: 94237	Exporting (certifying country): United States of America
	Importing (requesting country): Canada
1. Name and dosage form of the product: Metformin Hydrochloride – 1 pill = 500 mg	1.1. Active ingredient(s) and amount(s) per unit dose: Ingredients shown on attached document, amount depending on patient 1.2. Is this product licensed to be placed on the market for use in the exporting country? (yes/no) 1.3 Is this product actually on the market in the exporting country?: Yes
	If the answer to 1.2. is yes, continue with section 2A and omit section 2B. ~~If the answer to 1.2 is no, omit section 2A and continue with section 2B:~~
Section 2	2.A.1. Date of issue: 1995 (original) 2.A.2. Product licence holder (name and address): Bristol-Myers Squibb Company - **345 Park Ave, New York, NY 10154, United States** 2.A.3. Status of product licence holder: Active 2.A.4. Is a summary basis for approval appended? (yes/no): **On attached document** 2.A.5. Is the attached, officially approved product information complete and consonant with the licence? (yes/no/not provided) ~~2.A.6. Applicant for certificate, if different from licence holder (name and address):~~ ~~2.B.1. Applicant for certificate (name and address):~~ ~~2.B.2. Status of applicant: (Key in appropriate category as defined in footnote 8)~~ ~~2.B.2.1. For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:~~ ~~2.B.3. Why is marketing authorization lacking? (not required/not requested/under consideration/refused)~~ ~~2.B.4. Remarks:~~
Section 3	3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (yes/no/not applicable) If not or not applicable, proceed to question 4. ~~3.1. Periodicity of routine inspections (years):~~ ~~3.2. Has the manufacture of this type of dosage form been inspected? (yes/no)~~ ~~3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization? (yes/no/not applicable)~~
Section 4	4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product: (yes/no) ~~If no, explain:~~ Address of certifying authority: 70 Colombine Driveway, Ottawa, ON K1A 0K9 Telephone: (613) 957-2991 | Fax: 613-941-5366

Appendix D: Glossary

Term	Definition / Explanation
Proof of Concept (POC)	Understanding of a method/idea in order to demonstrate its feasibility, or a demonstration with the aim of verifying that some concept or theory has practical potential.
Java	Widely – used programming language Used Java to create app in Android studio
Back – End database	A database that users access indirectly through an external application (ex: app). Used Firebase's database component because it stores information easily and has a lot of security
QR code	Two – dimensional barcode that contains information. Readable by smartphones. Pharmacy or Doctor gives medication alongside with QR code that contains information about pill.
QR code scanner	An app or piece of technology that reads and displays the content in the QR code. Users can use a built – in QR code scanner in MedSafe app
Application Programming Interface (API)	A software that allows an application to get information (ex: Uber uses PayPals API to secure payments, Google uses an API for maps) MedSafe used Android Studio's API
Patient profile	Listing of data gathered on an individual patient. MedSafe allows patients to create and store their patient profile under their PHIN number.
Pill Profile	Listing of data on an individual pill. MedSafe allows users to scan their Pill QR code and see the pill profile
Certificate of Authority (COA)	A government-issued certificate authorizing the authenticity of a certain pill. In MedSafe once the patient scans the pill QR code they can see the COA issued by the government.
3D edible QR code medicine	A new method for production of medicine. Researches print out a pill with a QR code on edible material.

	QR code that patients can scan with their phones could pave the way for personalized medicines. The materials used to produce is safe for human consumption. Project plans to use this method in future science fairs.
GITHUB	Open platform for software developers to collaborate and share codes together.
Android Studio	The official platform/environment for developers to make Android applications using Java, Kotlin or C++. MedSafe is written and developed in Android Studio using Java
Software Development Kit (SDK)	A collection of software development tools all in one package.
Distributed network	A network that allows different machines to communicate and accomplish goals do that the whole server keeps running indefinitely.
Distributed Database	A collection of multiple interconnected databases that are physically located across various locations.
Distributed Computing	A model where the components of a software system are shared and distributed among multiple computers to improve efficiency and performance.
Hyperledger Blockchain	A project that aims to build an open source blockchain. Meaning users can make their own simple blockchain in a user-friendly environment.
Subscription Model	The subscription business model is a business model in which a customer must pay a recurring price at regular intervals for access to a product.
3D Printed Pills	For precision and personalised medicines. The ability of 3D printing to produce medications to exact specifications tailored to the needs of individual patients. The technology allows pills to be precisely printed in shapes, sizes and textures that are difficult to produce using traditional production techniques. Helps patients with multiple chronic conditions no longer have to take numerous drugs several times a day - instead they can take one pill containing all the required medications, once-daily, thanks to 3D printing.

Table 2: Glossary

Appendix E: References

1. United Nations (UN) Office of Drugs and Crime
   - https://www.unodc.org/unodc/en/frontpage/2019/May/unodc-launches-a-guide-to-combat-falsified-medical-product-related-crime.html?ref=fs1
   - https://www.unodc.org/documents/treaties/publications/19-00741_Guide_Falsified_Medical_Products_ebook.pdf
2. World Health Organization (WHO)
   - International Medical Products Anti-Counterfeiting Task Force (IMPACT)
3. Institute of Medicine (IOM)
4. Pharmaceutical Security Institute (PSI)
   - The Pharmaceutical Security Institute (PSI) is a not-for-profit, membership organization dedicated to:
     - Protecting the Public Health
     - Sharing Information on the Counterfeiting of Pharmaceuticals
     - Initiating Enforcement Actions through the Appropriate Authorities
5. https://link.springer.com/article/10.1007/s11277-020-07041-7
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11. Counterfeit Pharmaceutical Inter-Agency Working Group Report to the Vice President of United States and to Congress. https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/IPEC/Pharma_Report_Final.pdf Accessed Feb 9, 2020.
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