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An exploratory study of Finnish Medicines Verification Systems (FiMVS) alerting processes technical performance

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Medical safety through medicine falsifications entering the legal supply chain of medicines have become a serious safety issue in the European Union (EU). This study is concerned with the Finnish Medicines Verification Systems (FiMVS) alerting process which purpose is to tracks down falsified medicines. The system sets an alert if something is wrong with the verification (system related defects or potential medicine falsification). The purpose of the study is to offer more in-depth knowledge about the alerting system and study aims to give an overview of the implementation of the FiMVS. The role of the pharmacists doing the verifications is also put under the microscope. Mixed method was used as the methodology, mixing quantitative and qualitative data. Quantitative data was an alerting data straight from the system, which was the main focus of the study. This data was supported with qualitative interviews of the pharmacists.

The results shows that the amount of the monthly system alerts were lowered more than 80% during the data collection period. Other findings were that most of the alerts were data related and caused by pharmaceutical companies' improper feeding of data into the system. Pharmacists as users emphasized that thorough instructions are needed in reacting to the system alerts. Pharmacists also noted that medical safety can be improved with decreased amount of dispensing errors due to verification but the verification slows their work a bit.

The results lead to the conclusions that the overall performance of the systems alerting process improved during the data collection period and actions held to lower the amount of alerts had worked. Potential suggestions for the future includes actions streamlining the work of the pharmacists in an alert situation.

Keywords	Falsified Medicines, Medicines Verification System, EMVO, FiMVO, FiMVS, Medicine Falsifications, Medical safety.

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1 Introduction

The study is involved in prevention of medicine falsifications and the formerly announced European Union's (EU) Falsified Medicines Directive (FMD, DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL) and its supplementary delegated act (COMMISSION DELEGATED REGULATION, (EU) 2016/161). The FMD introduces certain safety features that drug packages dispensed within the EU are to include. The FMD came to force by the 9th of February 2019. Bringing the FMD into action, EU organized Medicines Verification system to prevent falsified medicines from entering the legal supply chain of the medicines. Finnish Medicines Verification Organization (FiMVO) is the responsible organization for the implementation of FMD in Finland. (FiMVO, 2018)

The purpose of the thesis is to evaluate the readiness of the Finnish Medicines Verification systems (FiMVS) alerting process and pros and cons of the implementation of the system. The FiMVS raises an alert if the data encoded in the data matrix on the pack does not match the data uploaded in FiMVS or pack status does not correspond to the transaction performed. Alerts can be technical (for example an inappropriate feed of the information in to the system or the drug package is not in the system or failed reading of the 2D barcode) or potential medicine falsifications. This thesis focuses on the core reasons behind the alerts and how the pharmacists perceived the readiness of the system and if and how the alarms affect their work.

FiMVS involves many different stakeholders including pharmaceutical companies, pharmaceutical wholesalers, pharmacies etc. The pharmacist's role at the pharmacy in the end of the supply chain must be very clear when the system is making alerts, because the pharmacist must react to the reasons of alerts quickly and it should not be disturbing the dispensing of the medicine to the customer. The alerting process had this so-called "soft launch" when most of the alerts are not in the way of making successful dispensing. The action phase of the alerting system started on February 2020. Alerting data for this study was collected from the beginning of the FMD (9th May 2019) and continuing until the end of July 2019. The results gives an overview of the implementation of the FiMVS and the development of system alerts during the first months after the implementation.

The concerns that the Medicines verification system is dealing with are the medical safety overall and making different parties involved in the supply chain via verification

system to operate in a firm cooperation. The literature review here combines these key concerns and sums them with research questions for this thesis as follows.

“From a technical perspective, what are the reasons for the alerts to be activated and can this activation be lowered?”

“How do the pharmacist perceive their readiness to work with the verification system?”

The data for the thesis was collected with qualitative and quantitative research methods to seek for the root causes for the alerts. The data includes quantified alert data from the verification system on an Excel form together with six interviews of the end-users of the supply chain, the pharmacists, with semi-structured interviewing. The alerting data was analyzed using Alteryx Designer, a data-analyzing tool that helped in gathering key information from the various Excel-spreadsheets (Alteryx, 2021). The interviewing data was analyzed using Thematic Analysis method. In the analysis and discussion section, the data reveals findings as to the potential causation of the alerts and offers comprehensive overview of the FiMVS alerting process and pharmacists perceptions towards the system.

2 Medication safety & Medicines Verification system

This chapter introduces the reader the importance of the verification system. First, patient and medical safety overall are introduced leading to falsified medicines and to prevention of these medicine falsifications. After that, a couple of management strategies are introduces to offer guidance for how to firmly organize processes such as medicine verification system is and finally the system, Medicines Verification System itself is introduced.

2.1 Patient and medical safety

All over the globe, the health care organizations are managed and organized differently but one connecting thing for all is to ensure the safety of patients. (Lewis & Fletcher 2005: 135.) For health care organizations to cope better with the government-initiated strategies in improving patient safety, they must understand the reasons for complex managing changes in health care. They must also widen the perspective of thinking how

to successfully implement improvements in patient care (Lewis & Fletcher 2005: 138). Even though there have been many improvements towards better patient safety, the overall rates of harm to patients has not been identified. Managing safety and quality better among the health care are key factors in decreasing the patients harm rates (Braithwaite & Donaldson 2016: 326).

The quality of patient care can be improved through successful medication management (Bush & Daniels 2014: 177.) One big issue concerning patient safety are the prescription medicines sold without a prescription. Often in these cases, the medicines are being used without suitable instructions and that leads to ineffective and potentially dangerous abuse of medicines. Reasons for this kind of self-medication are the low accessibility to health care providers, inefficiency and bad quality of public health (or the presumption of this) and a low percentage of health-insured individuals. (Bigdeli et al 2014: 34).

Inappropriate use of pharmaceuticals is dangerous for health, expensive and it worsens the inequities and unbalances the sustainability within health systems. Bigdeli (et al 2014:45) claims that half of the primary care medicines are prescribed or dispensed inadequately. Inadequate medicines distribution has also been linked to two thirds of the total health care expenditures in Low and Middle Income Countries (LMIC's) (Bigdeli et al 2014: 45).

According to studies, adverse drug events are on the sixth position causing deaths (Tamblyn et al 2012: 2). Approximately 7% of all acute care hospital admissions are related to such events. More than half of these are preventable. Typically, the adverse drug events are errors in dispensing or prescribing, over or underuse of drugs or incorrect information given about the medicine. (Tamblyn et al 2012: 2). These are significant numbers and important to take into consideration when it comes to patient safety.

One very important factor among the medication safety are also the substandard or falsified medicines (SF). Substandard and falsified medicines are a growing threat especially in the low- and middle-income countries (LMICs). Through globalisation, it is becoming a more familiar threat also in developed countries. Main problems faced from the increase of SF medicines are the lack of faith towards the pharmaceuticals, controlling of diseases gets harder and complications related to therapies happens more often, antimicrobial resistance weakens in the long-run and expensiveness of all of this (Rasheed et al 2018: 995). Estimation of the costs is 45 billion Euros per annum (Religioni et al

2017: 1). As health care resources are very scarce, Bigdeli et al (2014: 45-46) claims medicines are responsible for three of the 10 most resource wasting units of the health care resources. These three wasting sources are overpriced medicines, SF medicines and the misuse of medicines. (Bigdeli et al 2014: 45-46)

2.2 Substandard and falsified drugs

The consequences of the SF medicines are remarkable for health but for the economics as well. Commonly accepted definition for substandard drugs is as follows: "*authorized medical products that fail to meet either their quality standards or specification, or both*" (Ozawa et al 2018: 2) This may be a result of low-quality manufacturing, wrong shipping and storage conditions or the medicine sold after its expiration date. Falsified drugs are defined as "*products that deliberately/fraudulently misrepresent their identity, composition or source*". (Ozawa et al 2018: 2). FMD (FMD, DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL) defines falsified medicinal product as falsely presenting its identity (package, label, name or its consistence and/or strength), source (place of manufacture, Marketing Authorization holder (MAH)) or anything related to its history (records, documentation or delivery routes). It is good to notice that the FMD does not concern quality issues that occur by mistakes and not on purpose. (FMD, DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL)

This means that substandard and falsified (SF) drugs often appear like normal medicine packages but they contain only inactive ingredients, right active ingredient but the dosage is wrong or SF drugs may include contaminants or the drug has expired. These SF drugs can be extremely harmful and in the worst case, lethal. Low quality antibiotics weakens the antibiotic resistance, which spreads highly resistant pathogens worldwide. The SF drugs causes many expenses and as a side effect SF drugs may also decrease the confidence towards the authentic medicines (Sylim et al 2018: 2).

Within the LMIC's, there is a real challenge in securing good quality of medicines. Reasons for these challenges are on the managing side that the different stakeholders have not made real settlements on how to manage such quality issues within medicines. Therefore, there is not enough regulatory capacity and the fact that there is not enough

reliable data on how to deal with different kinds of problems that leaves testing and monitoring the data in weak hands. These issues leave a playground for the SF medicines especially in LMIC counties. (Bigdeli et al 2014: 34).

Within developed countries where market security and control are implemented, the amount of falsified medicines inside the legal supply chain is estimated to be approximately 1%. (Merks et al 2016: 11.) That is one medicine package out of one hundred. When going to the most eastern parts of Europe, to the former Soviet Republic countries, the prevalence is even much higher, 10-20%. (Merks et al 2016: 11.). Going further in to LMIC's, into some regions of Africa, Asia or South America almost one third of the legal supply chain medicines are falsified. The falsifications enter the European markets through those gateways. (Merks et al 2016: 11).

World Health Organization's (WHO) standards in evaluating medicines appropriateness for certain diseases and accessibility for United Nation's (UN) agency and LMIC suppliers includes acceptable quality, safety and efficacy measurements of the medicines. Throughout the supply chain of medicines, there must be conversation between different stakeholders. Within different parties of the supply chain and the system must feature inexpensive and fast technologies in monitoring the quality of the drugs. (Bigdeli et al 2014: 34).

2.3 Preventing medicine falsifications

Medicine falsifications are one very significant factor affecting the patient safety worldwide, which makes it a very important factor of public health. (Włodarczak et al 2017: 1) There are several different information technology tools in preventing SF medicines, such as medicines authentication tools (MAT), 2D barcoding in different types of alert systems, radiofrequency identification tags, visual inspection easing databases and anti-tampering devices. (Rasheed et al 2018: 995).

2.4 Managing the supply chain

The supply chain of drug distribution involves many different parties – manufacturers, wholesalers, and community and hospital pharmacies. All of these stakeholders needs

to perform in a good harmony considering the Medicines Verification system. (Włodarczak et al 2017: 1) This subchapter introduces supply chain management and process management as management strategies with which the context of the study is approached.

2.4.1 Supply Chain Management

The operating of the different stakeholders related to the Medicines Verifications System must be fluent. Managing such supply chain involves integrated planning, controlling and coordination of the required business solutions to add value for the consumer. (Jack & Van Der Vorst 2004: 6) In the framework of this thesis, the benefit for consumer can be seen as the decreasing amount of the alerts made. For a company to succeed they should re-think their processes from individual business processes within the company to integrated business processes over co-operating organizations within the company's supply chain. (Jack & Van Der Vorst 2004: 8)

2.4.2 Process management

As has been described earlier, this study's deeper interior is focusing on patient safety and quality. Enhancing safety and quality in health care acquires strong leadership and management as well as teamwork. The culture of the organizations should also be encouraging and ahead aspiring. The core of any health care related system is to thoroughly answer the needs of the patients. The oxford handbook introduces reasons for unsafe care where counterfeit and falsified medicines are considered among key processes contributing unsafe care. (Braithwaite & Donaldson 2016: 325-328)

Effective process management involves taking the blame of harms from an individual more towards to general attitudes and what actually is going on in the system. Streamlining and designing of current activities creates efficacy. These changes does not come without cost however and it makes systems and processes complicated and hard to manage. According to Braithwaite & Donaldson (2016: 337), commonly used strategies for this type of systems that seeks for streamlines and efficacy are system redesign, business process re-engineering and lean. Common for these strategies is that those argue that people, departments and technology are the linkage parts within an organization. (Braithwaite & Donaldson 2016: 329, 337)

Braithwaite & Donaldson (2016: 338) argues that safety and risk-management of organizations requires effective leadership. Safety and risk-management are also praised in an organization where flexibility and a feeling of belonging is presence. Multilateral health care systems makes it hard to implement change among health care related organizations and especially on those where safety and quality are on concern. (Braithwaite & Donaldson 2016: 338-339)

One of the stumbling blocks among safety and quality processes is that the atmosphere and attitudes are praising harms and highlighting errors and faults instead of focusing of what is done correctly within an organization. Fixing and correcting these errors requires the previously mentioned methods where standardizing and streamlining are the cures. Braithwaite & Donaldson (2016:341) also brings forward the fact that sometimes focusing on what is done right (which usually is, what an organization mostly does) brings up effective ways, ideas and models to learn and highlight also that what is done right. (Braithwaite & Donaldson 2016: 341-342)

Santos et al (2014: 1081) identified several indicators that are advantageous in measuring the success of a project. These include technical performance of the organization, effectiveness in managing through the project, personal growth of the involved employee and success and outputs of the project including customer satisfactory. Santos et al (2014: 1082) also adds that according to studies made by major American consultant firms, the most important factor of measuring project succeeding is the customer satisfaction followed by quality and monetary values. (Santos et al. 2014: 1081-1082)

FiMVS involves many different stakeholders and many supply-chains of medicine delivery why choosing supply-chain management as an approach of the study was quite natural. Building up a completely new system like FiMVS is requires strong process management skills. In addition, its complex character and the presence of safety & quality approach made the process management suiting the context well.

2.5 Medicines Verification system

Medicine falsifications harms the work of every part of the legal supply chain of drugs but also policymakers who are responsible for the safe delivery of drugs not to mention

the end-users of the chain, the people who consumes the drugs. Food and Drug Administration (FDA) in the United States of America (USA) has set up a global action against falsified medicines of which the European Union (EU) is a part of. (Włodarczak et al 2017: 1) The changed EU legislation concerning falsified medicines, Falsified Medicines Directive (FMD) came lawful at February 9th 2019. (DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL) The FMD was introduced with the delegated act that separates the detailed rules demanded for the different drugs and drug types involved in the FMD. The FMD introduces safety features for every drug packages for identifying certain package and securing its authenticity. These safety features include unique identifiers and anti-tampering mechanisms. These actions are held to prevent medicine falsifications from entering the market within the EU. (COMMISSION DELEGATED REGULATION (EU) 2016/161) These actions of the EU FMD also improves pharmacotherapeutic safety of the patients by monitoring the distribution of drugs. The required verifying mechanisms are set to secure the authenticity of the drugs inside the EU. (Włodarczak et al 2017: 1)

Verification or authentication of the drug package being dispensed includes scanning the pharmaceuticals with a unique 2D barcode and an anti-tampering device that shows whether the medicine package has been tampered. On the final stage of the supply chain the pharmaceutical is decommissioned out of the system. After the verification, if everything is the way they are supposed to be the medicine package can be dispensed to the patient or if not then it may need to be quarantined (Rasheed et al 2018: 995). If there is something wrong with the verification the system sends an alert to separately selected parties involved to the verification system (FiMVO, EMVO, Authority (Finnish Medicines Agency (FIMEA)), wholesalers, Pharmaceutical companies etc.) and the needed actions are held to see whether the alert is technical or a potential falsification. (FiMVO, 2020: 5.) These alerts also apply the pharmaceutical wholesalers. (Rasheed et al 2018: 995.) In Finland, falsified medicines entering the legal supply chain are very rare. Falsified medicines have been found three times in hospital pharmacies within public health care never from outpatient pharmacies (FiMVO, 2021). In the late 2017 and during the summer 2018 parallel imported cancer medicines entered the legal supply chain in Finland and at least the other was also used as treatment for 30 to 50 patients. (Fimea 2018; Fimea 2018). The prevalence of the falsifications entering the legal supply chain is not frequent, but these cases emphasizes that functioning medicines verification system is important also in Finland.

In the European level the responsible party in implementing the medicines verification system is EMVO (European Medicines Verification Organization) and at a national level NMVO (National Medicines Verification Organization) (Włodarczak et al 2017: 2). For example, in Finland FiMVO (Finnish Medicines Verification Organization). Main task of the NMVO is to create a database for the authentication of medicine packages. (Włodarczak et al 2017: 2; Commission Delegated Regulation (EU) 2016/161) The functioning of the system must be performed cost-effectively, securely and in an interoperable way. (EMVO, 2019)

The implementation of the medicines verification system requires well organized workforces, awareness, and knowledge to deal with such wide spreading legal regulations. Pharmaceutical industry's role is very important in building the EU's medicines authentication system. According to Włodarczak (et al 2017: 2, 6) studies, the readiness of the pharmaceutical industry managers for the medicine verification system was insufficient at the time of their studies. (Włodarczak et al 2017: 2, 6).

3 Purpose, aims & objectives

The purpose of the thesis is to offer more in-depth knowledge to FiMVO about the alerting data and give an overview of the implementation of the FiMVS. The study focuses to explore the technical reasons behind the alerts that the system is sending and that way helping in the fight against medicine falsifications. Through the alerting data, the importance of the soft launch period is also evaluated. Besides the alerting data, the study focuses on the role of the pharmacists dispensing medicines, whom are hence directly involved with the system. Aim of the study is to help securing the firmness and streamlines of the pharmacists work during the dispensing process.

Based on the indicated factors, object of the study is to offer answers to the research questions of the thesis:

1. From a technical perspective, what are the reasons for the alerts to be activated and can this activation be lowered?
2. How do the pharmacist perceive their readiness to work with the verification system?

4 Setting

This chapter introduces the parties involved in the verification system. First, briefly, the executive body in the European level, EMVO, is presented. After the executive organization in Finland, FiMVO is presented and then key points of the FMD and Commissions Delegated Regulations are introduced.

4.1 EMVO

The European Medicines Verification Organization's (EMVO) mission is in securing safety of the European pharmaceutical market. EMVO's responsibilities include the advancing of the European Medicines Verification System's (EMVS) functioning and secure, interoperable and cost-effective implementation In the Europe following the FMD and DR of the EU legislation. EMVS's area of responsibility has been in setting up of the European HUB database, where all the National Medicines Verification Systems (NMVS) are connected. (EMVO, 2019)

4.2 FiMVO

In Finland, the responsible organization of administrating the Medicines Verification System (MVS) is the Finnish Medicines Verification Organization (FiMVO) which is a non-profit company as is regulated by the EU legislation. FiMVO's responsibilities concerning the MVS are to ensure that the system is operating following the EU legislations and build up the database that all the actors among the Finland's medicines legal supply chain are instructed to join. (FiMVO, 2019)

Finnish Medicines Verification System (FiMVS) is connected to the EMVS that is the executive unit within the EU. EMVO have created the database, European HUB, into which pharmaceutical companies feed the information needed of each medicine package. From the EU Hub product and package data are transferred to national systems

(e.g. FiMVS) to which local pharmacies and wholesalers have connected as is implemented in Figure 1. Organizational structure of the medicines verification system. (FiMVO, 2018; FiMVO 2019).

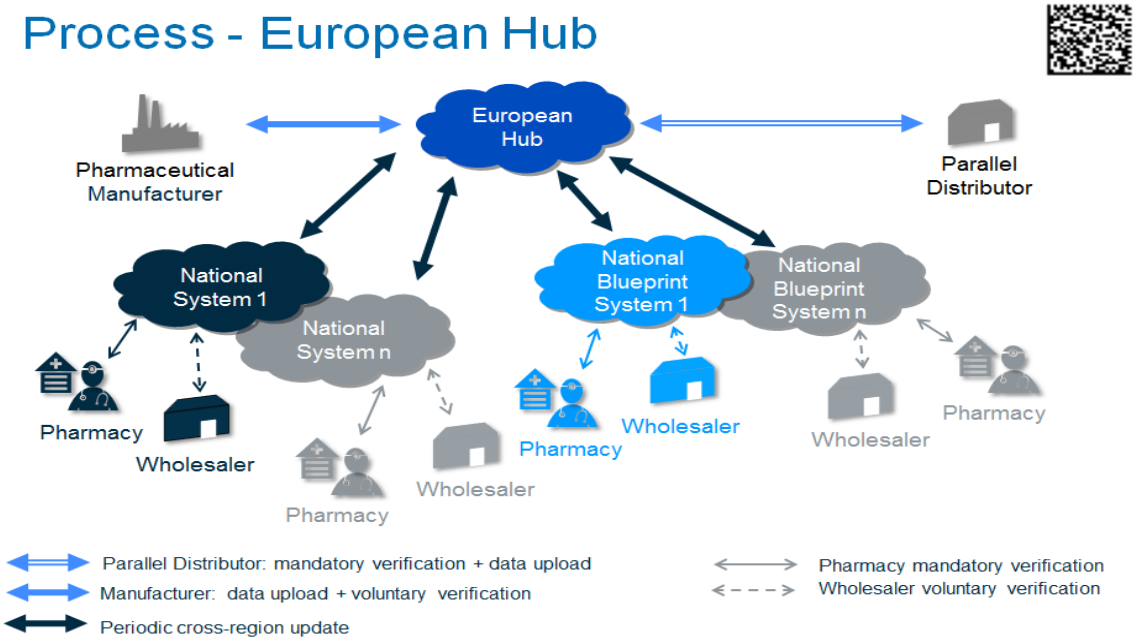

Figure 1. Organizational structure of the medicines verification system. (FIMVO, 2018)

Verification or authentication includes scanning the pharmaceuticals with a unique 2D barcode and an anti-tampering device that shows whether the medicine package have been tampered or if it is authentic. (Rasheed et al 2018: 995.)

4.3 FMD & COMMISSION DELEGATED REGULATION

This chapter introduces the key points of the Falsified Medicines Directive and its delegated regulations (FMD, DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL; COMMISSION DELEGATED REGULATION, (EU) 2016/161):

The purpose of the new directive is in preventing falsified medicines entering the legal supply chain of medicines for human use in EU. The directive applies especially to prescribed medicines. The amount of falsification inside the Union have been increasing lately so much that actions are needed. This has caused worry of medical safety and the lack of trust towards the legal supply chain. Complex supply chains makes the problem more complicated and so the parties involved in the distribution or wholesaling of medicines are to perform in accordance with the directive. (FMD, DIRECTIVE 2011/62/EU

OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL; COMMISSION DELEGATED REGULATION, (EU) 2016/161)

Directive introduces the safety features that the drug packages are to feature and the Delegated Regulations defines these more thoroughly. Different safety features improves patient safety and the required randomized unique codes also helps managing recalls, withdrawals and other returning activities. A two-dimensional (2D) barcode can hold more information than other type of data contents and in addition to this, the verification data should be also in a readable form. Anti-tampering device is the other safety feature that secures the authenticity. (FMD, DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL; COMMISSION DELEGATED REGULATION, (EU) 2016/161)

EU defines falsified drugs as follows:
Falsified drugs presents incorrectly the identifying information including the package and packaging label, name, relation of all the ingredients and strengths. Also, the origin of this information or the product history are presented incorrectly with falsified medicines. The Directive emphasizes that unintentionally incorrectly presented information does not fulfil the criteria of a medicine falsification. (FMD, DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL)

5 Materials & Methods

This chapter introduces reader the research methods used in the study and explains the reasons why these methods were chosen in this thesis' context. In addition, the datatypes analysed are introduced.

The background of the study started when the researcher was working at a pharmacy and before the implementation of the FiMVS there was a trial of the system offered to the pharmacies and that way the curiosity of researcher towards the system was awaken. After that, the researcher contacted directly to FiMVO and the quantitative analysis of the systems alerting data became a mutual interest and something that would potentially be beneficial to secure fluent dispensing of pharmaceuticals also after the soft-launch period. Since the researcher was working at a pharmacy, the perspective of the pharmacists was obvious to choose for the qualitative part of the study. With mixing the research

methods, the study dives more in-depth to the role of the pharmacists at the end of the supply chain.

5.1 Mixed Methods

The study is a case study combining qualitative and quantitative research methods. This combining of both research methods is called mixed methods. Qualitative research method explore attitudes, behavioral and experience point of view to seek deeper opinions and experiences from the participants of the study. Results of qualitative researches are usually gathered with interviews or focus groups. As the characteristic of qualitative research is seeking deeper opinions and experiences it involves lesser participants, but they are more deeply involved. (Dawson 2002: 14-15, 20).

Quantitative research method is based more on statistics using for example large-scale surveys or questionnaires. (Dawson 2002: 15) The quantitative research often comes together with concepts like reliability, validity and generalizability. (Noble & Smith 2015: 1). Quantitative research is based on a research problem that the research seeks for answers. (Kananen 2011: 20-21.) The reason that this thesis deals with both, quantitative and qualitative research methods is because the study is seeking to find results in both types of problems, dealing with users experiences as in qualitative research and also to find answers to questions like “how many” or “how often” as in quantitative research. (Dawson 2002: 20) In this study, these are considered as the experiences of the pharmacists in the last stage of the supply chain verifying the package out of verification system and the quantitative data is collected of the alerting data that the system is sending about the alerts. The reason for using the mixed methods as an approach is to seek as deeply as possible to the core reasons of the alerts and to help the end-users to be able to act as fluently as possible during the alerting situations at the future. Through mixed methods, the study seeks to offer more insight and deepen the understanding behind the studied phenomena.

5.2 Alerting data

The verification system is sending an alert when something is wrong with the verification or authentication of the verified drug package. Alerts can be technical or caused by human error (for example an inappropriate feed of the information in to the system or the

drug package is not in the system or failed reading of the 2D data matrix) or potential medicine falsifications.

Quantitative approach was used in gathering information of the alerts launched from the beginning of the verification system, from the 9th of February 2019 and continuing for six months until the end of July 2019. It was agreed with the QA manager of FiMVO that they would deliver researcher the alerting data monthly in an Excel spreadsheet. Researcher's task as a participant observer was to analyze the data taking into an account the different alarm types and different parties (pharmacies, hospital pharmacies, wholesalers etc.) directly involved in the FiMVS. In the participant observation, the researcher collects and performs the results. An advantage of the participant observation is that the researcher is directly involved in to the context of the research. (da Silveira e Silva et al 2012: 120) The role of the researcher's participation was to offer FiMVO an overview of the first months of the FiMVS after the FMD came to force.

The alerting data was received and then analyzed using the data-analyzing tool Alteryx Designer. With Alteryx, analyzing multiple Excel sheets simultaneously becomes more efficient and creating automated workflows with which different datasets can be analyzed faster. (Alteryx, 2021) Figure 2 shows an example of the workflow created with Alteryx Designer. In the workflow, the data from Excel sheets is imported to the Designer to be modified into the wanted direction to get the desired results. The data analyzed is approached with different perspectives to get answers for the alerts as widely as possible. The analyzing of the alerts is important in developing the alerting system and making the dispensing more fluently done in a trustworthy manner and following the EU legislations.

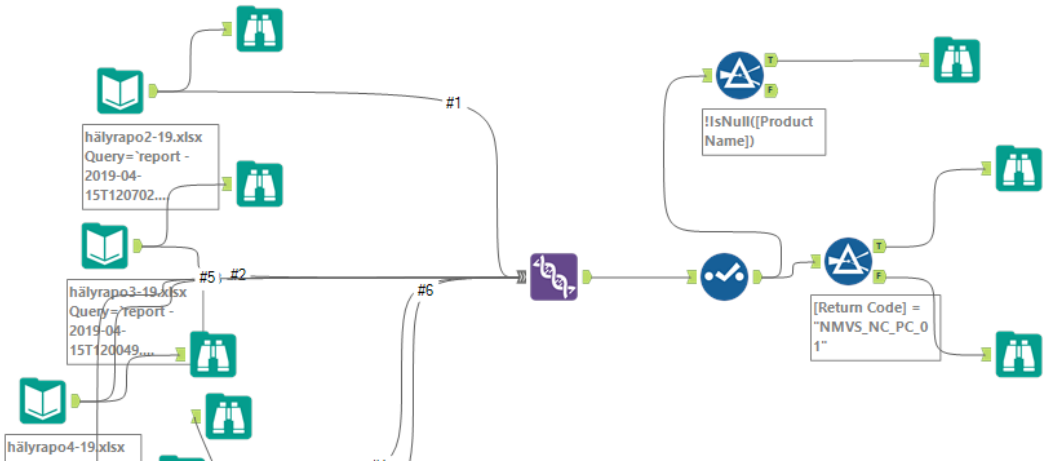

Figure 2. Workflow built with Alteryx Designer to analyze the alerting data

The deviations in verifying the medicine packages are set on five different levels of which the level 5 (L5), actual alerts, are on concern of the study (FiMVO 2020: 5). The different L5 type alert types are presented on table 1.

Table 1. Different alerting codes of the system

NMVS_NC_PCK_27	Status change could not be performed
NMVS_NC_PCK_06	Actual pack status doesn't match the undo transaction (set and undo status must be equivalent).
NMVS_FE_LOT_12	Expiry date does not match the date held in the NMVS.
NMVS_FE_LOT_03	Failed to find a batch for the given data.
NMVS_NC_PCK_22	Pack is already inactive.
NMVS_NC_PCK_19	Property is already set on pack.
NMVS_NC_PCK_23	Re-setting of the property via double scan is registered.
NMVS_FE_LOT_13	The batch ID does not match the serial number in the NMVS.
NMVS_NC_PC_01	Unknown product code.
NMVS_NC_PC_02	Unknown serial number.

While dispensing the medicine at the pharmacy the pharmacist scans the 2D barcode (see figure 3) of the medicine package.

Figure 3. An example of the data that the 2D Data matrix contains.

The examples below are demonstrated with the Maxx-pharmacy IT software. The successful scanning does not provide a positive feedback, but the status of the scanned medicines goes 0/1 -> 1/1 (if there is one package to verify). If there is something wrong with the verifying (reading the 2D data matrix), the Pharmacy system signs an alert, for example (Figure 4.): (Receptum, 2021)

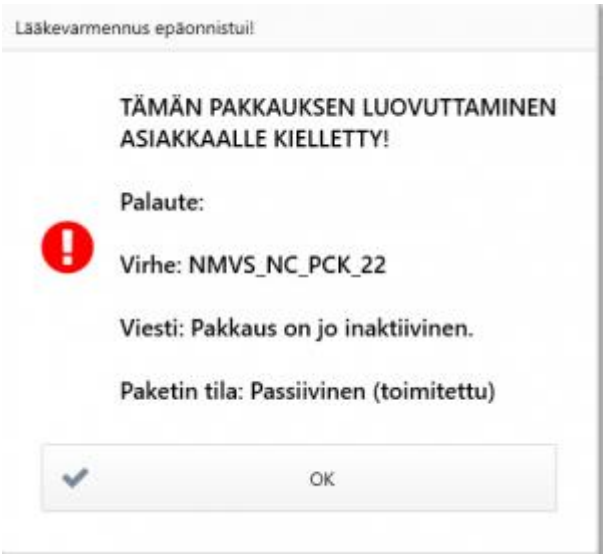

Figure 4. An example of an alert (MAXX software)

Here the pharmacist should know how to react to the different types of alerts. Apteekkariliitto (The Association of Finnish pharmacies) and pharmacy IT-software providers have delivered the instructions to the pharmacies on how to react when the system launch an alert. Often, the pharmacist has a very little time to react to the alerts and while dispensing the medicine the customer is physically there and delays will affect the customer service (Lahtinen & Isoviita 1998: 64.) Elements that an organization should take into consideration within customer service highlights the waiting time for the service and the expertise of the customer service person (Lahtinen & Isoviita 2000: 64.) These are just a couple of reasons why the verification should go as smoothly as possible at the pharmacy not affecting the service situation negatively.

5.3 Interviewing of pharmacists

The interviews were kept as semi-structured interviews. Reason for choosing semi-structured interviewing for the study is because the study seeks to find specific information about the Pharmacist's readiness to react to the alerts. So, asking the same questions within each interview is the most effective way of doing the interviews and leaving open questions at the end allowing flexibility to the interview and possibility to possible important factors affecting the Pharmacists role that have been left without attention. (Dawson 2002: 28-29)

The qualitative research method is used for making the interviews to pharmacists and how they feel about the verification system and is it affecting negatively or positively their work is evaluated. Offering helpful information through the data collected may offer improvements for guidelines of the Pharmacists so their tasks during the alerts would get clearer.

The interview consists of the following questions presented:

1. “What pharmacy it-software the pharmacy that you are working in is using?”
2. “How have you felt the Verification system have affected your work?”
3. “Is it clear to you what to do when the system makes an alert?”
4. “Do you feel like you have got enough instructions to react to alerts when it happens?”
5. “What kind of instructions and guidelines would you like to have for the alerts?”
6. “Should the Maxx/Salix/PD3/apteekkariliitto offer better instructions in reacting to alerts at the time of an alert?”
7. “Should the codes of the alerts be opened more so that would help the possibly busy decision during the alert?”
8. “Are you aware, or would you like to be aware, of what is making the alerts? Would you like that the IT-software that you are using tells you that more precisely?”
9. “Any other comments or concerns about the verification system or your role as a pharmacist in it”?

The interviews were held in Finnish and the results contains a total of six interviews with pharmacists. For contacting potential pharmacists to participate in the survey, the researcher had asked Apteekkariliitto (The Association of Finnish pharmacies) to add a note of the study for volunteers into Salkku (Intranet for all pharmacies). The note was later seen to be placed into some outdated forum and was there out of its context. This in part explains the rather low number of interviewed pharmacists, because the information considering the study was hard to find from the Salkku.

Interviews were held face-to-face (one interview), through email (two interviews) or printed papers shared at workplace and returned as answered (three interviews). The interviews were kept within the last quarter of the year 2019. The results were translated from Finnish to English to the results of the study and the one face-to face interview

transcribed. Below, in table 2 is presented the transcribed and translated answers to the questions and in the appendices (appendix 1) is the gathering of the interviews. In the answers, the researcher have added the questions inside the brackets for clarification.

Table 2. Answers of the pharmacists.

Questions	**Answers**
1. "What pharmacy it-software the pharmacy that you are working in is using?"	MAXX, MAXX; MAXX; MAXX; MAXX;PD3
2. "How have you felt the Verification system have affected your work?"	- Dispensing taking a bit more time (especially if many packages), on the other hand, you don't have to open the anti-tampering device anymore to stick the plasters, which saves time. Dispensing errors occurs seldomly because all the packages are reflected to the purchase through verification. - I do not feel that it has made a big difference. - Slows down the dispensing a bit but also decreases the amount of dispensing errors. - Slows down a bit when the packages (verification?) needs to be awaited/ to pick up the packages before you can continue from the end-info. Good that the verification allows you to double-check the packages. - Easy, no problems, one routine task among others. - "Beeping" of the products slows down the dispensing a bit.
3. "Is it clear to you what to do when the system makes an alert? What kind of problems have you faced and how have you started solving them?"	- There has been only a few alerts, we do have written instructions for such cases. Only one that I have faced so far is the "unknown product code" and it does not cause actions at this phase. - Any bigger problems have not arisen. A bit unsecure how to proceed. I will check our instructions and ask from colleagues. - It is clear. If there are uncertainty, our pharmacy has good instructions in case of a problematic situation. - It is not clear, I have not faced problems yet, I would first check our pharmacy's instructions and if needed, ask from colleague/supervisor. - I do know where to seek for answers in a problematic case. No issues have arisen so far. - It is clear, we have good instructions for these.
4. "Do you feel like you have got enough instructions to react to alerts when it happens?"	Yes; Yes; Yes; No I don't feel; Yes; No I don't.

5. “What kind of instructions and guidelines would you like to have for the alerts?”	- Our instructions have been sufficient. On the other hand, there have not been many alerts. - Regular reminders how to react. Easy to find instructions. - Our pharmacy has thorough instructions. - Precise and explicit instructions for all types of alarms. - Instructions should be simple enough and easy to find. - What needs to be done and what (possibly) is wrong with the medicine (verification?).
6. “Should the Maxx/Salix/PD3/apteekkariliitto offer better instructions in reacting to alerts at the time of an alert?”	-I can't tell - Some common instruction would be good to have. - I believe not. - Yes - No - Yes.
7. “Should the codes of the alerts be opened more so that would help the possibly busy decision during the alert?”	- Of course it would help if in the case of an alarm there would be a quick information, whether this needs to be reacted or is it just a package that needs to be verified manually. - Yes, clear note where and what is the problem. - It would be nice to know what is causing the alerts. - Yes! - Yes, the codes are complicated. - I really do not understand anything about the codes so yes those could be more understandable.
8. “Are you aware, or would you like to be aware, of what is making the alerts? Would you like that the IT-software that you are using tells you that more precisely?”	- I can't tell. - There is information available, but not so easy to find. I would like to know that what is causing the alert when it happens. - I wish and would like to know better. - I would like to know more, the IT-system could inform more clearer + tell me what to do. - Yes. - This would be nice but not necessary. Of course it would make the customer communications easier.
9. “Any other comments or concerns about the verification system or your role as a pharmacist in it”?	No; empty; Empty; Empty; No :) ; Better informing and reminders of the mode of actions.

These answers are opened more in the results and discussion sections.

5.3.1 Thematic Analysis

Thematic analysis method was used for analysing the data. Thematic analysis is commonly used qualitative analysis method, which is praised for its elasticity and accessibility. Characteristic for thematic analysis method is that it observes and analyses themes from the data. Themes are perceived as picking research question related fruits out of data. These pick-ups also form patterns making linkages between one another and creating subthemes. Other advantages thematic analysis share is that even a big amount of data can be summarized with it and the theming of data shows similarities and differences of the data well. (Braun & Clarke 2006: 4-10, 27)

Braun & Clarke introduces a six-step guidance for conducting a thematic analysis (Figure 5). Braun & Clarke (2006:16) emphasizes that data analysis is not as linear as the figure might address, rather going up and down the steps during the analysis.

Phase	Description of the process
1. Familiarising yourself with your data:	Transcribing data (if necessary), reading and re-reading the data, noting down initial ideas.
2. Generating initial codes:	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching for themes:	Collating codes into potential themes, gathering all data relevant to each potential theme.
4. Reviewing themes:	Checking in the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic 'map' of the analysis.
5. Defining and naming themes:	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells; generating clear definitions and names for each theme.
6. Producing the report:	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of the analysis.

Figure 5. Phases of Thematic Analysis (Braun & Clarke 2006: 16-23)

Because of the accessibility and usability of the method, thematic analysis was selected as a tool to analyse the interviewing data. The study presents qualitative data alongside the quantitative data to deepen the focus of the pharmacists in the verification process. As has been described earlier, pharmacist linkage towards the verification system is notable. Qualitative data also seeks to find if there are potential development suggestions available towards the pharmacist's role in the verification process that has been overlooked earlier.

5.4 Case study

Case studies are often related to qualitative studies but can also be used for quantitative research. Case studies are used when the research focuses on multiple details of a case (or cases). (Neuman 2014: 42). Case study seeks to understand and explain thoroughly the case and its causes and effects in its real-life context. Case studies also allow interventions and involvement. (Crowe et al. 2011: 1-4, 8; Neuman 2014: 42) Among the above-mentioned characteristics, the researcher's involvement directly to the alerting data of the verification system gives the quantitative research a characteristic of a case study.

5.5 Validity & reliability

Validity and reliability means that any errors considering the data should be avoided. The data should be relevant. The meter used in the study is valid if it answers the research problem. (Kananen 2011: 118) As research questions include the following "what are the reasons for the alerts to be activated and can this activation be lowered", the meter of measuring the alerting data through quantitative data collection can be noticed as valid.

Reliability refers to the stability or repeatability of the results of the study. The results should not leave space for randomness. (Kananen 2011: 118) The results of the alerting data during the data collection period are stable and so the results can been seen as reliable. Reliability and validity always goes hand by hand, reliability can be high but if the meter used in study is not valid, the results may be inadequate. Here Kananen (2011: 119) uses an expression of a poorly directed rifle, you may get a flat set but it is not even

near the bullseye. (Kananen 2011: 118-119) The rather low number of interviews lowers the reliability of the interviews that is good to take into an account at the discussion section.

Analyzing techniques and expected results may be hard to predict because of the variable information in the alerts. The readiness of the pharmacists is expected to be in sufficient level. Since the verification system is new, all helpful data and information concerning the verification system is useful for all the stakeholders involved in the alerting process.

6 Results

6.1 Alerting data

The alerting data gathered from the alerting system was analysed and various different aspects taken into an account. Successful dispensing via verification system starts from the pharmacist reading the 2D barcode from the medicine package. The 2D barcode includes the following data that must be correct or the system sends an alert: product code (14 digits), serial number (variable length (max 20) of alphanumeric characters), Batch ID (lot number) that also includes max 20 alphanumeric characters and expiry date. If one or more of the codes is fed incorrectly from behalf of the Pharmaceutical Company, the Pharmacist's 2D data matrix reader falsely reads the code or the undo transaction is misused then the alert is sounded. Fourth element that the verification includes is the expiry date that needs to be fed correctly to the system. There might be certain country specific requirements considering the form of date (for example DD/MM/YYYY). In Finland, the date is always represented as YYMMDD or YYMM00 (which means the last date of the month in question). (FiMVO, 2020: 12) The 2D data matrix includes all of these elements but the codes must also be presented as in human readable form in case of disorder in reading the 2D data matrix. (EMVS, European Pack Coding Guidelines).

Next, the study presents the alerting data. Figure 6 below shows an example of what the alerts looks like in Excel.

Time	Exc	Return Code	Return Code Description	Product Code	Product Name	Batch Id	Serial No	Client Id
11.4.2019 10:46	L5	NMVS_FE_LOT_03	Failed to find a batch for the given data.	##############	XXXXXX	**0009	*********We	DISPENSARY
11.4.2019 10:47	L5	NMVS_FE_LOT_03	Failed to find a batch for the given data.	##############	XXXXXX	**0009	**********7F	DISPENSARY

Figure 6. An example of an alert

Figure 7 shows that the total amount of alerts decreased rapidly after the start of the soft launch from Februarys almost 31 thousands to Julys just over 6 thousand alerts.

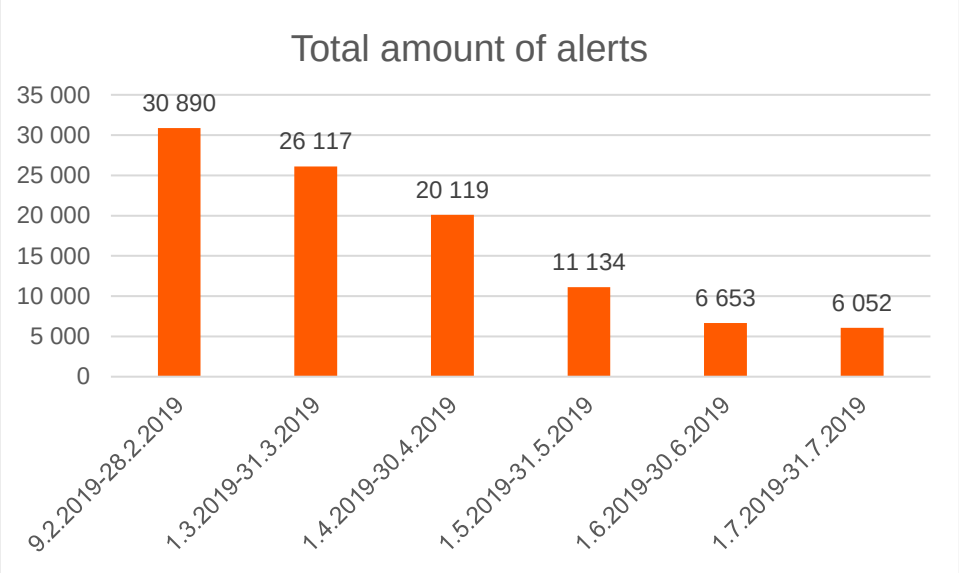

Figure 7. Total amount of alerts

Figure 8 shows all the alerts per alert type. Three tallest bars are marked as red as those were the type of alerts that were not in a way of dispensing the medicine into a patient during the soft launch. These represents 78,3 percent of total alerts during the data collection period.

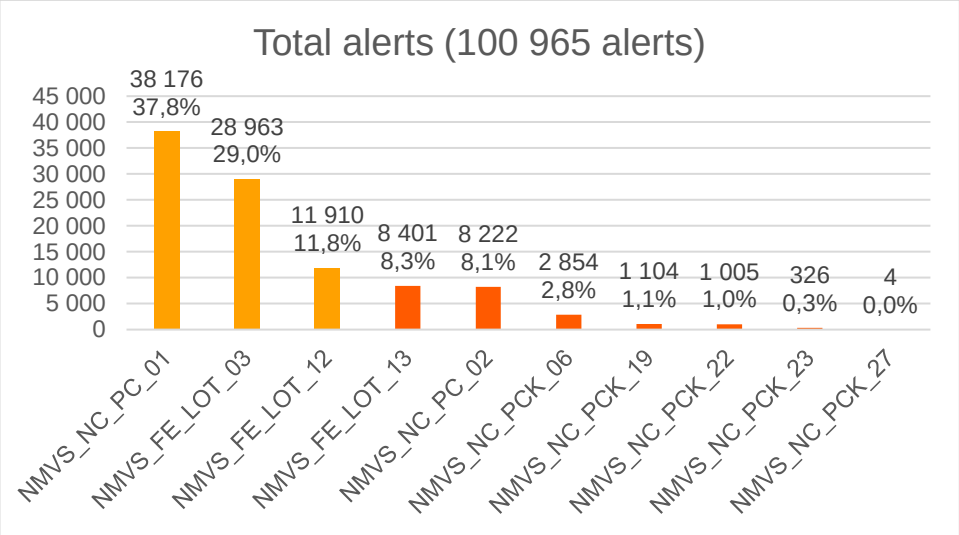

Figure 8. Different alerts, total

Table 3 shows the same results with reason codes in the more readable form.

Table 3. Different alerts, total

Unknown product code.	NMVS_NC_PC_01	38 176
Failed to find a batch for the given data.	NMVS_FE_LOT_03	28 963
Expiry date does not match the date held in the NMVS.	NMVS_FE_LOT_12	11 910
The batch ID does not match the serial number in the NMVS.	NMVS_FE_LOT_13	8 401
Unknown serial number.	NMVS_NC_PC_02	8 222
Actual pack status doesn't match the undo transaction (set and undo status must be equivalent).	NMVS_NC_PCK_06	2 854
Property is already set on pack.	NMVS_NC_PCK_19	1 104
Pack is already inactive.	NMVS_NC_PCK_22	1 005
Re-setting of the property via double scan is registered.	NMVS_NC_PCK_23	326
Status change could not be performed	NMVS_NC_PCK_27	4

Next, the study is going to dig deeper to the core reasons behind different alerts.

6.1.1 Opening the alerts code by code

NC_PC_01 Unknown product code *38 176 alerts*

As was mentioned earlier, proper product code (PC) (or GTIN) consist of 14 digits. Other instructions for PC guided by the European Pack Coding Guidelines (EMVS, European Pack Coding Guidelines) includes that the first digit is 0 (“leading zero”). GTIN used for

medicines is normally in GTIN-13 form where is this “leading zero” and last digit is the “check digit” meaning that it is calculated from all the digits of certain GTIN. Figure 9 from GS1 instructions demonstrates how the GTIN’s are structured. (GS1 Healthcare GTIN Allocation Rules Standard 2020: 33)

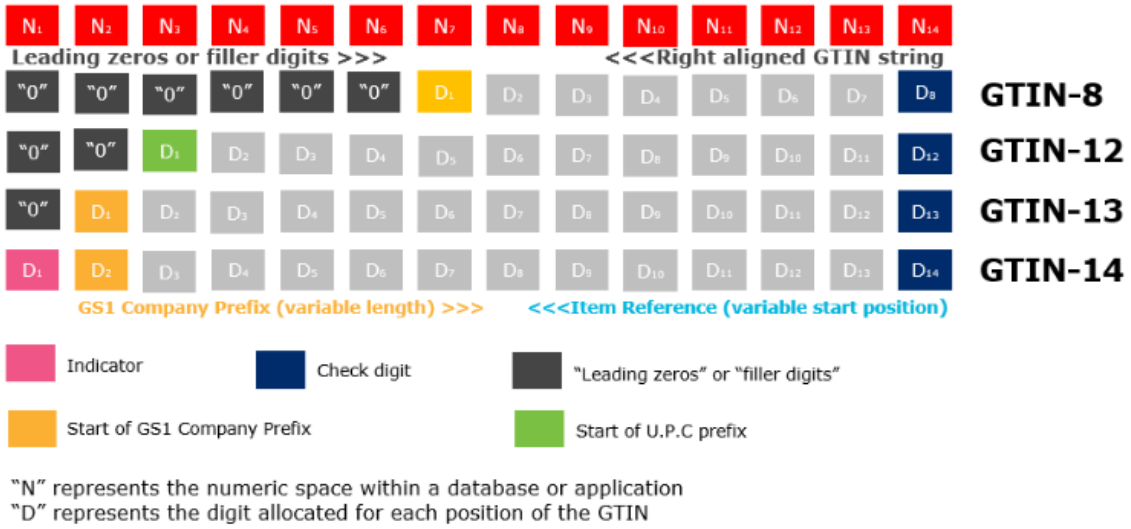

Figure 9. Form of GTIN code (GS1 Healthcare GTIN Allocation Rules Standard 2020: 33)

48 percent (17 569 alerts) of the NC_PC_1 alerts had as digits 2, 3 & 4 code -890. 37 percent had the fifth digit 3 (as -8903). Not all of these had the leading zero.
33 percent (12 432) had the code sequence 7046 after the first digit. Same pattern applied here that the first digit was found to be something else than 0 (here also 1 or 3).
12 percent of the alerts came from one product code (pollen season medicine) mostly during the springtime. Figure 10 shows the NC_PC_01 alerts divided by different types of product codes.

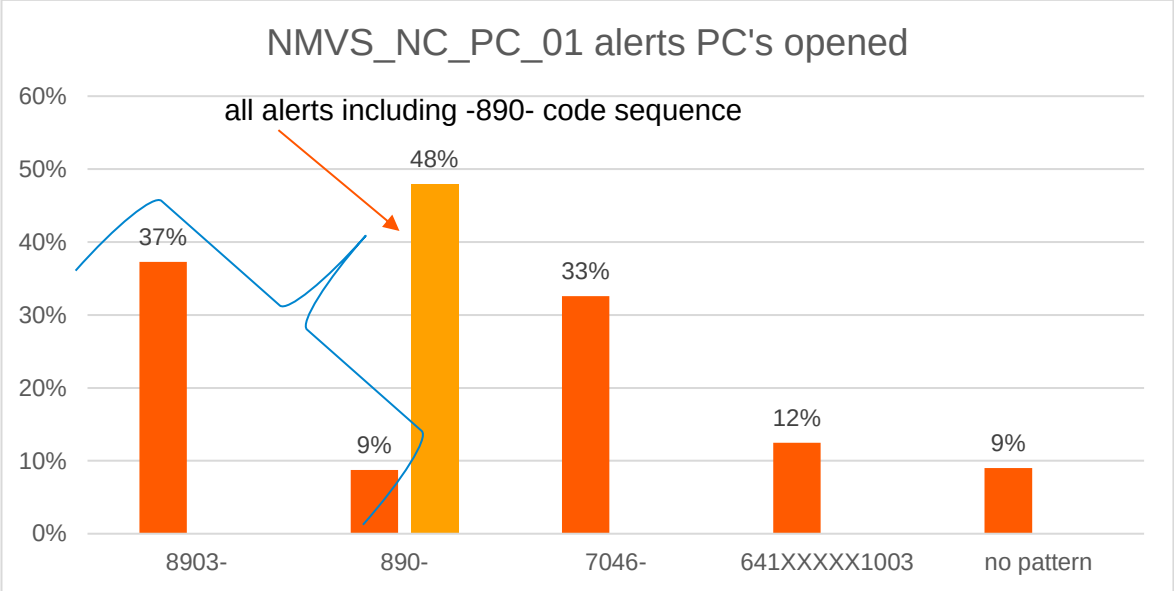

Figure 10. NMVS_NC_PC_01 alerts PC's opened

Rest (nine percent) of the alerts recurred maximum 656 times per one product code and had not visible pattern for which the alerts occurred. Alerts might had only one digit (0 --> 64 alerts) or 5 or some other false number of digits.

FE_LOT_03 Failed to find a batch for the given data *28 963 alerts*

European Pack Coding Guidelines instructs Batch code as follows:
"Batch code is a variable length field of up to 20 alphanumeric digits followed by a Group Separator (GS) character (to delimit it from the next field unless it is the last field)" Batch code is also advised to introduce the below rules (EMVS, European Pack Coding Guidelines):

- *"The alphanumeric range shall include the digits 0-9 and the letters of the western alphabet but exclusion of the following letters: i, j, l, o, q and u. (I J L O Q U) might help avoid confusion with similarly shaped characters/numerics.*
- *The serial number character string should only contain either lower case or upper case letters, not a mixture.*
- *Use of the extended symbols, should ideally be avoided."*

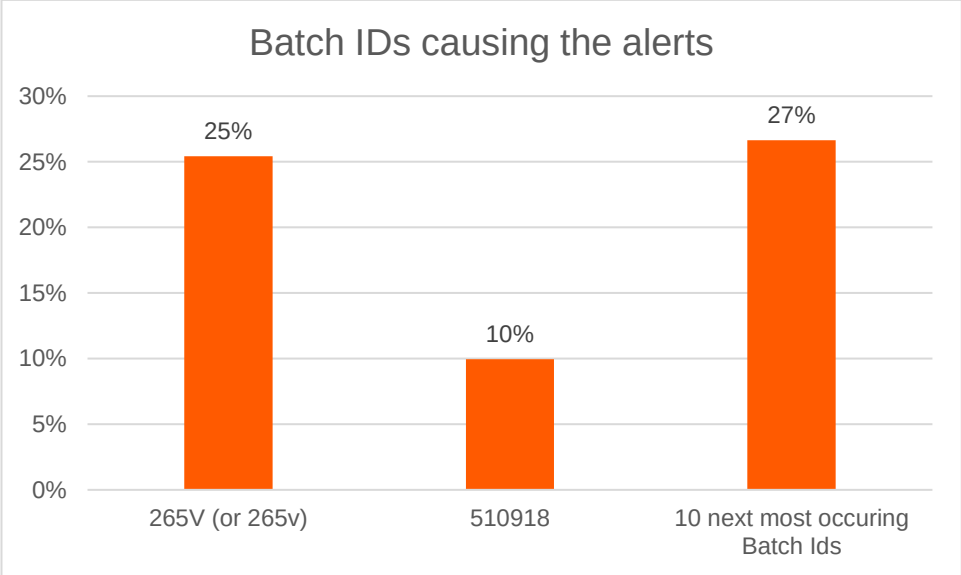

Figure 11. Batch IDs causing the most of the FE_LOT_03 alerts

Twelve most occurring Batch IDs causing almost two thirds of all FE_LOT_03 alerts (Figure 11).

FE_LOT_12 Expiry date does not match the date held in the NMVS 11 910 alerts

The improper feeding of expiry dates become a big cause of alerts from March until May as Figure 12 demonstrates.

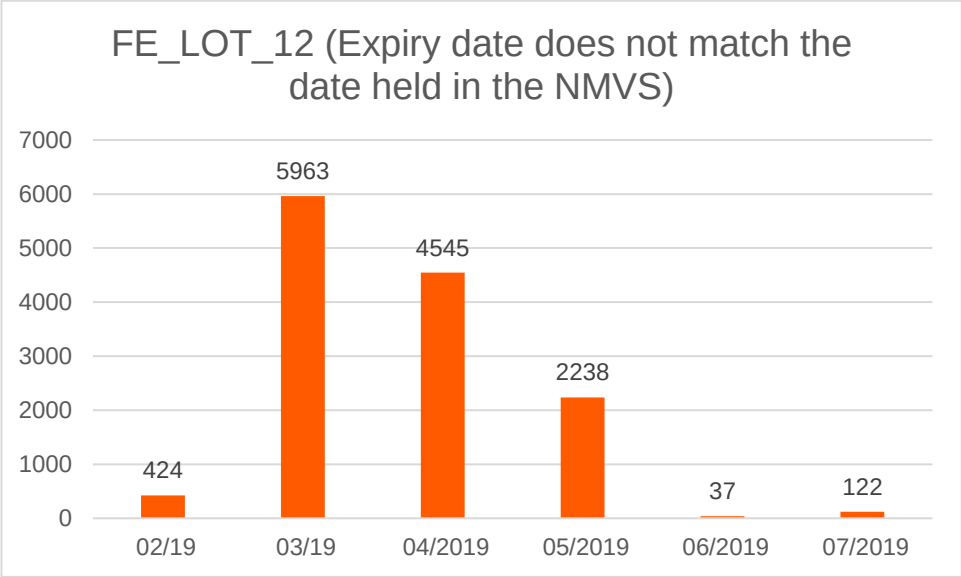

Figure 12. Alerts caused by incorrectly fed expiry dates

FE_LOT_13 The batch ID does not match the serial number 8 401 alerts

These are the alert types where serial number (SN) is correct and the Batch ID does not match it. Two most occurring Batch IDs caused 28 percent of these alert types (Figure 13).

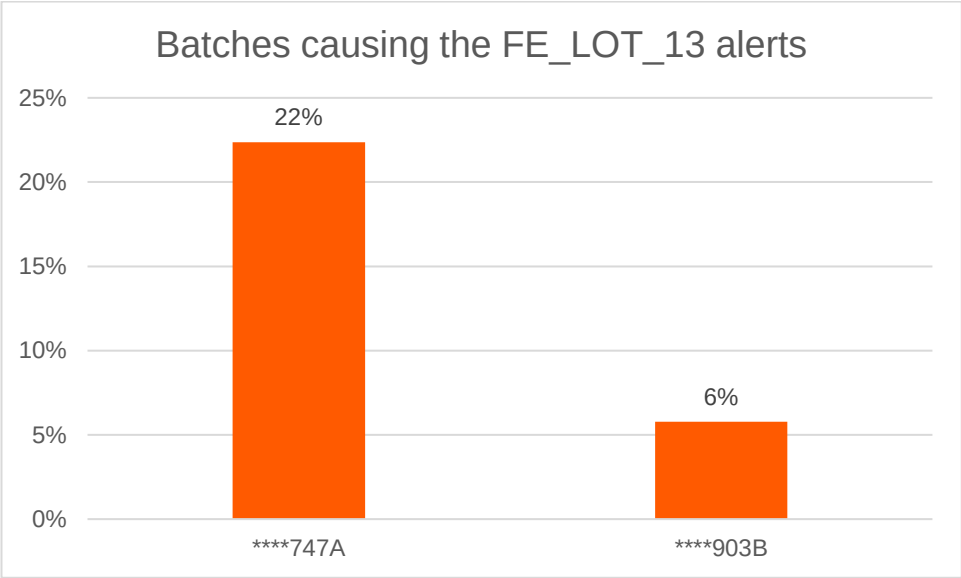

Figure 13. Examples of Batch ID's causing FE_LOT_13 alerts

Figure 14 shows another example of different alerts for the same product. In the upper alert, Product Code is read also to the Batch ID. Serial number here is correct so the return code is the FE_LOT_13.

Return Code	Return Code Description	Process Name	Product Code	Batch Id	Serial No
NMVS_FE_LOT_13	The batch ID does not match the serial number in the NMVS.	Dispense single pack	**********844	***245**********844	**********151
NMVS_NC_PCK_22	Pack is already inactive.	Dispense single pack	**********844	***455	**********179

Figure 14. An example of FE_LOT_13 alert

NC_PC_02 Unknown serial number *8 222 alerts*

European Pack Coding Guide sets same basic standards for Serial Numbers (SN) as there is for Batch ID's (EMVS, European Pack Coding Guidelines): *"is a variable length (up to 20) alphanumeric field followed by a Group Separator (GS) character (to delimit it from the next field unless it is the last field)"*.

NC_PC_02 alerts consisted of 5049 different serial numbers (of 8 222 alerts). One SN appeared maximum of 62 times. Same PC appeared in these alerts maximum of 658 times.

NC_PCK_06 Actual pack status does not match the undo transaction (set and undo status must be equivalent). *2 854 alerts*

All the NC_PCK_06 alerts were divided between seven different PC's (Figure 15). 99,9 percent of these alerts came from hospitals.

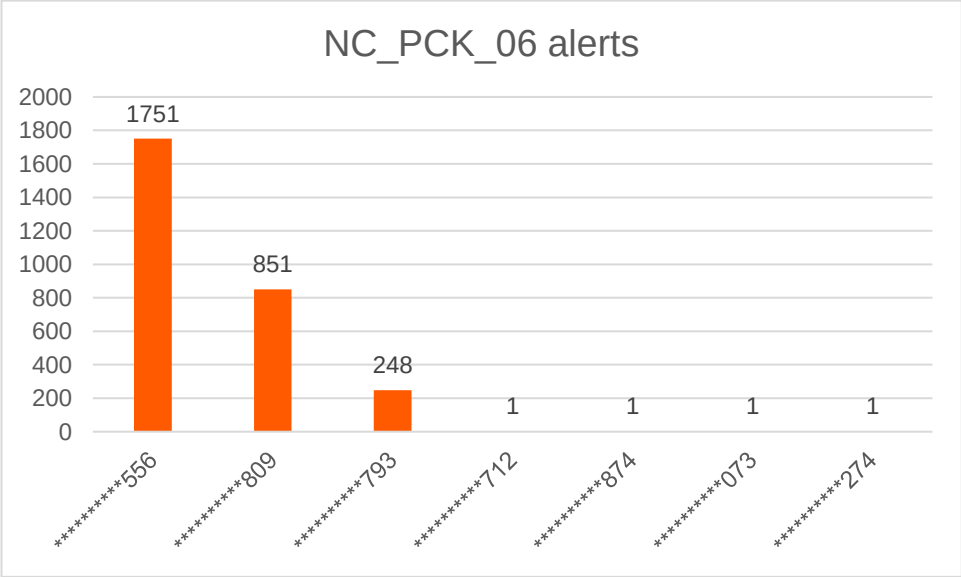

Figure 15. NC_PCK_06 alerts divided by Product codes

The same batch ID caused 1005 alerts on June 2019 data. The single pack that have made an alert every 5 minutes created a total of 999 alerts (998 NC_PCK_06 alerts) (Figure 16).

Time	Return Code	Return Code Description	Process Name	Product Code	Batch Id	Serial No	Client Id
13.6.2019 10:38	NMVS_NC_PCK_06	Actual pack status doesn't match the undo transaction (set and	Undo dispense single pac	**********556	1100521A	********8579	HOSPITALPHARMACY
13.6.2019 10:38	NMVS_NC_PCK_06	Actual pack status doesn't match the undo transaction (set and	Undo dispense single pac	**********556	1100521A	********8298	HOSPITALPHARMACY
13.6.2019 10:38	NMVS_NC_PCK_06	Actual pack status doesn't match the undo transaction (set and	Undo dispense single pac	**********556	1100521A	********5925	HOSPITALPHARMACY
13.6.2019 10:10	NMVS_NC_PCK_22	Pack is already inactive.	Dispense single pack	**********556	1100521A	********8298	HOSPITALPHARMACY
13.6.2019 10:12	NMVS_NC_PCK_22	Pack is already inactive.	Dispense single pack	**********556	1100521A	********8579	HOSPITALPHARMACY
13.6.2019 10:28	NMVS_NC_PCK_22	Pack is already inactive.	Dispense single pack	**********556	1100521A	********5925	HOSPITALPHARMACY
20.6.2019 14:14	NMVS_NC_PCK_22	Pack is already inactive.	Dispense single pack	**********556	1100521A	********6481	HOSPITALPHARMACY
20.6.2019 14:15	NMVS_NC_PCK_06	Actual pack status doesn't match the undo transaction (set and	Undo dispense single pac	**********556	1100521A	********6481	HOSPITALPHARMACY
20.6.2019 14:20	NMVS_NC_PCK_06	Actual pack status doesn't match the undo transaction (set and	Undo dispense single pac	**********556	1100521A	********6481	HOSPITALPHARMACY
20.6.2019 14:25	NMVS_NC_PCK_06	Actual pack status doesn't match the undo transaction (set and	Undo dispense single pac	**********556	1100521A	********6481	HOSPITALPHARMACY
20.6.2019 14:30	NMVS_NC_PCK_06	Actual pack status doesn't match the undo transaction (set and	Undo dispense single pac	**********556	1100521A	********6481	HOSPITALPHARMACY
20.6.2019 14:35	NMVS_NC_PCK_06	Actual pack status doesn't match the undo transaction (set and	Undo dispense single pac	**********556	1100521A	********6481	HOSPITALPHARMACY
20.6.2019 14:40	NMVS_NC_PCK_06	Actual pack status doesn't match the undo transaction (set and	Undo dispense single pac	**********556	1100521A	********6481	HOSPITALPHARMACY
20.6.2019 14:45	NMVS_NC_PCK_06	Actual pack status doesn't match the undo transaction (set and	Undo dispense single pac	**********556	1100521A	********6481	HOSPITALPHARMACY
20.6.2019 14:50	NMVS_NC_PCK_06	Actual pack status doesn't match the undo transaction (set and	Undo dispense single pac	**********556	1100521A	********6481	HOSPITALPHARMACY
20.6.2019 14:55	NMVS_NC_PCK_06	Actual pack status doesn't match the undo transaction (set and	Undo dispense single pac	**********556	1100521A	********6481	HOSPITALPHARMACY
20.6.2019 15:00	NMVS_NC_PCK_06	Actual pack status doesn't match the undo transaction (set and	Undo dispense single pac	**********556	1100521A	********6481	HOSPITALPHARMACY
20.6.2019 15:05	NMVS_NC_PCK_06	Actual pack status doesn't match the undo transaction (set and	Undo dispense single pac	**********556	1100521A	********6481	HOSPITALPHARMACY
20.6.2019 15:10	NMVS_NC_PCK_06	Actual pack status doesn't match the undo transaction (set and	Undo dispense single pac	**********556	1100521A	********6481	HOSPITALPHARMACY

Figure 16. An example of one package causing multiple NC_PCK_06 alerts

NC_PCK_19 Property is already set on pack. *1 104 alerts*

79 percent (869 alerts) came from one PC. Most of these cases happened as the example above sending an alert every 5 minutes. 85 percent of the alerts came from hospital pharmacies. 15 percent (111 alerts) of this alert type that came from the pharmacies had 96 different Serial numbers.

NC_PCK_22 Pack is already inactive *1 005 alerts*

NC_PCK_22 related alerts occurred with 390 different PC's (1005 alerts) and 74 percent of these came from pharmacies. One PC appeared a maximum of 26 times. This alert type occurs after a valid verification for authenticated packages.

NC_PCK_23 Re-setting of the property via double scan is registered 326 alerts

This alert type formed only a very small amount of total alerts (0,3 percent). 80 percent of the alerts came from pharmacies. Seven PC's (Figure 17) caused Four fifths of these alerts.

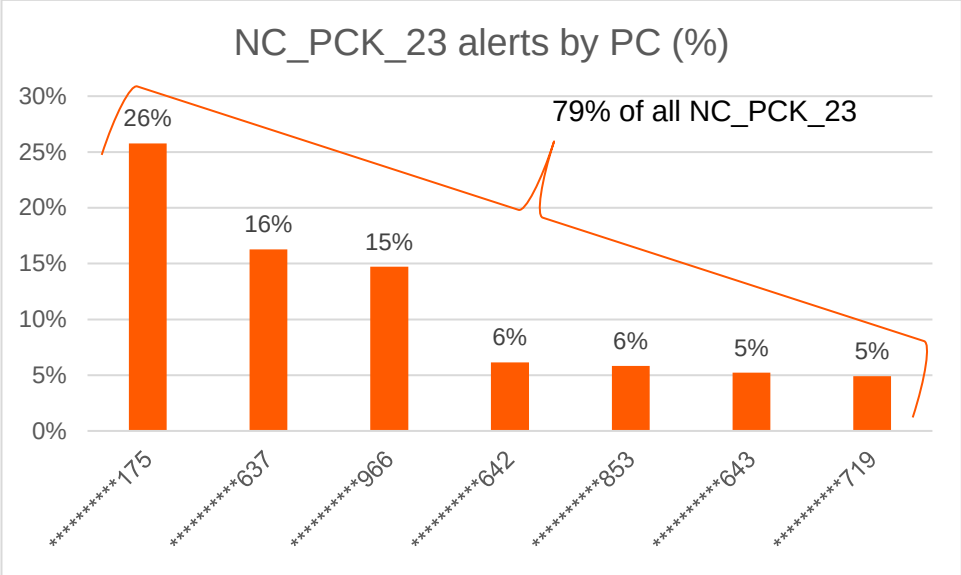

Figure 17. NC_PCK_23 alerts by Product code

Last alert type NC_PCK_27 “Status change could not be performed “, was reason behind four alerts.

Figure 18 shows that most of the alerts came from pharmacies. Other defined Clients were Dispensaries, Hospital pharmacies, wholesalers and “unknown”.

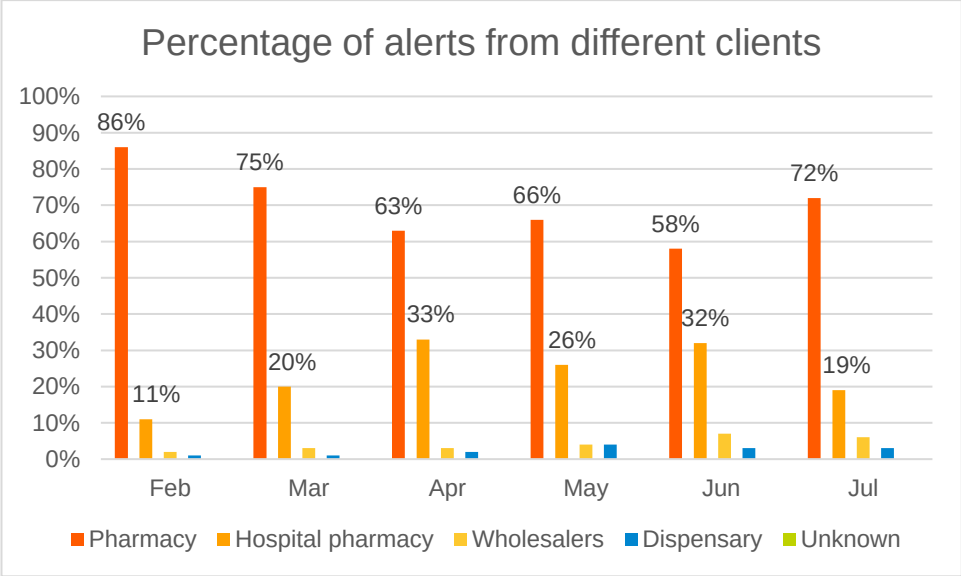

Figure 18. Percentage of alerts from different clients.

One aspect of the alerts is the “process name” where different options for values are as is presented in the figure 19.

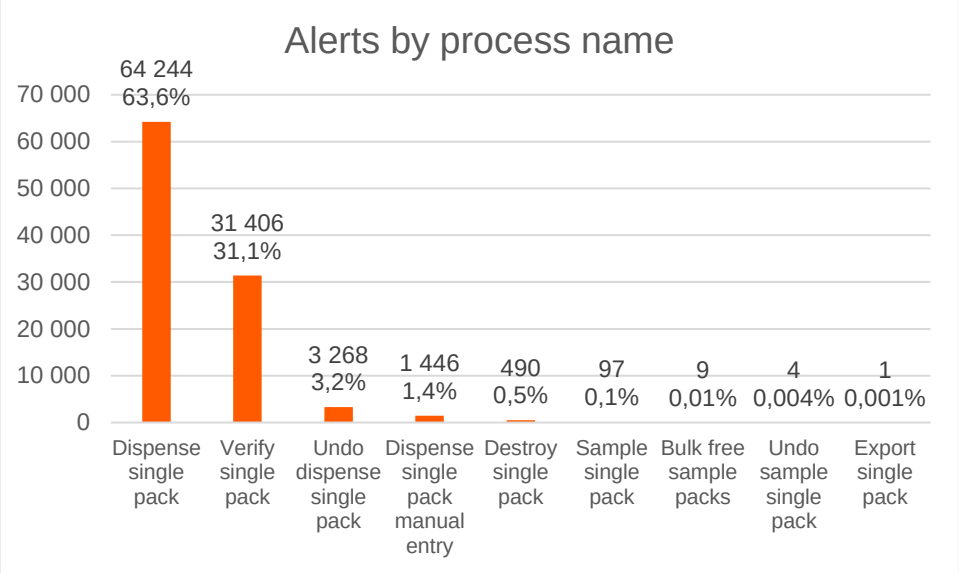

Figure 19. Alerts by process name

Next, the thesis introduces the other part of the data collection, interviews of the Pharmacists.

6.2 Pharmacists interviews

The interviews were kept face-to-face or as an email interview. In the email interview, the questions were sent to the answerer and returned as answered. The results consist of total of six interviewed Pharmacists. The answered Pharmacists were working with two out of three different Pharmacy it-software programs, Maxx and PD3. Salix users were not reached for the study.

Overall conclusions considering the interviews are listed below. Considering the question 2, “How have you felt that the Verification system have affected your work?” the answers varied a bit. Four out of six said it has slowed the dispensing a bit and two said that not much difference (Figure 20), one routine task among the others.

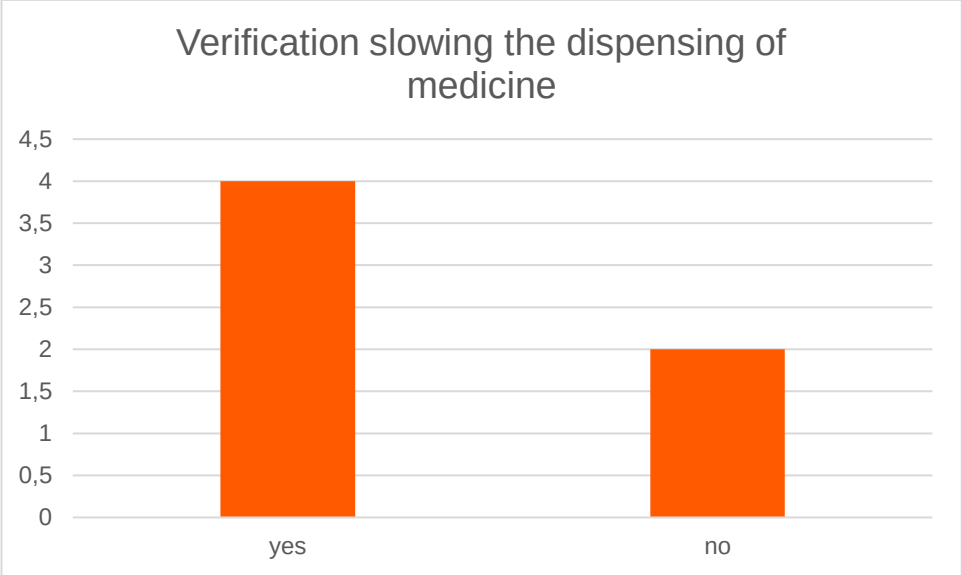

Figure 20. Verification affecting the dispensing.

One answer also pointed the advantage of the system as the dispensing is more secured when the Pharmacist scan the 2D-code, the verification basically allows no space for dispensing errors. For the third question “Is it clear to you what to do when the system makes an alert?” the Pharmacists almost unanimously answered that the readiness on reacting to alerts is in an appropriate level and that the pharmacies guidelines are clear in the case of an alert.

One third answered to the fourth question “Do you feel like you have got enough instructions to react to alerts when it happens?” that they have not get enough instructions on reacting to the alerts, rest said that their readiness is enough. Fifth question considering guidelines “What kind of instructions and guidelines would you like to have for the alerts?” pointed that the Pharmacists feel that their pharmacies have good and thorough instructions and guidelines. Some also mentioned that the guidelines should be easy to found and they should be simple enough to read in a dispensing situation. One point was also that the instructions should be reminded occasionally so that the readiness would be better when an alert is sounded.

On the sixth question considering the offering of better instructions, “Should the Maxx/Salix/PD3/apteekkariliitto offer better instructions in reacting to alerts at the time of an alert?” the answers varied. Half of the answerers said that better instructions are needed, one third said that the instructions are already thorough and one answerer left the question open, as “I can’t tell”. All the answerers wanted more information about the

codes of the alerts so it would streamline the reaction of the Pharmacist to the different types of alerts (Question 7 “Should the codes of the alerts be opened more so that would help the possibly busy decision during the alert?”).

For the question number eight “Are you aware, or would you like to be aware, of what is making the alerts? Would you like that the IT-software that you are using tells you that more precisely?” as well the answerers would like to have more information of the alerts to streamline the communication towards the customers and precise information would also make the role of the Pharmacist more confident when an alert is sounded. In the last open question better informing and reminders of the instructions is wanted from behalf of the Pharmacists.

7 Discussion

7.1 Alerting data

The alerting data from the data collection period highlights the importance of the testing period with such process. There were multiple reasons behind the high prevalence of alerts but during the testing period the alerts were able to be lowered with more than 80 percent from incomplete February to July (see figure 7). The alerting data does not take into an account the total amount of dispensed medicines from pharmacies but the data undeniably tells the fact that the alerts were lowered during the data collection period.

The reading of the alerting data starts from product code (defining the certain product). After that comes the Batch code defining the certain batch that the medicine package is a part of. Last the serial number that is unique for all the medicine packages in the EMVS requiring verification defining the one stock keeping unit (SKU).

According to Yrjönen (2019: 6), the alerts can be divided into two main categories:

- Data related errors (Pharmaceutical companies have fed insufficient/wrong data (considering product, batch or single packages serial number) into the system. Can be also caused by the user (errors in reading the 2D barcode of the package)
- alerts related to the status of the package (package is already inactive or the undo-transaction cannot be performed)

The alerts can be also divided by the causer:

- Pharmaceutical companies (Data errors)
- End-user (can be data or status errors: technical reasons or erroneous working methods

7.1.1 NC_PC_01

In the unknown product code (NC_PC_01) alerts there were certain code sequences ("-890-" and "-7046-") that repeated in 81 percent of all NC_PC_01 alerts. Product code is also known as GTIN (Global Trade Item Number). GTIN is a number sequence (GS1 Company Prefix) that holds the information of the country where the member organization have allocated the certain package (GS1 Healthcare GTIN Allocation Rules Standard 2020: 32). GS1 Company Prefix includes a list that shows all the countries company prefixes and the prefix 890- belongs to India (GS1 Company Prefix: 2021). The company prefix does not tell the manufacturing country, however. 17 569 alerts (17,4 percent of all alarm) had 890- company prefix. This finding argues that the owners of these GTIN-codes have allocated these packages to India. In India, similar demand of using a unique 2D barcoding was introduced earlier than in EU and every package manufactured (also imported/exported batches) were to introduce these features. (Bansal et al 2013: 8-9). Reason that these packages caused alerts was that the packages were released into the market before 9th of February 2019 and adding of the packages, released before that date, into the verification system was not compulsory. Later, after the data collection period NC_PC_01 "unknown product code" are no more classified as alerts but deviations (Yrjönen 2020: 5).

7.1.2 FE_LOT_03

Alerts FE_LOT_03 "Failed to find a batch for the given data" were the second most occurring alert type within the data collection period. Twelve most occurring Batch number's in this alert type represented two thirds of total FE_LOT_03 alerts. This highlights the importance of the correct data that the pharmaceutical companies feed to the system. On the other hand it tells the good part that the problem with Batch IDs was centralized more to these certain packages and that the problem wasn't that general. These alerts was also caused because of the batch data was not uploaded to the system (Yrjönen

2020: 10). Other explanation might be the same as above that, the packages had the 2D data matrix but the information was not fed into the system.

7.1.3 FE_LOT_12

The alerts caused by incorrect expiry dates (FE_LOT_12) is interesting. The data shows that in the first month of the data collection period the alerts were in low level but from March to May, these were among the most alert causing types. After this high prevalence period, the pharmaceutical companies had been instructed (EMVO letter of announcement, 2019) properly on feeding the expiry date in to the system and in June, the alerts had almost vanished (37 alerts vs. 5963 in March). This finding suggests that the notice send to pharmaceutical companies worked fast and effectively. According to the alerting data 87 percent of FE_LOT_12 alerts where from three different Marketing Authorizations Holders (MAHs), which explains that the problem was centralized to certain operators.

The low number in February might be explained with other reason codes taking the alerts (probably then FE_LOT_12 would have caused more alerts if other alert types could have been lower). These three previously mentioned did not prevent the dispensing of medicine to the customer/patient during the data collection period. Forthcoming alert types were to be clarified before the medicine could be dispensed out to the patient/customer.

7.1.4 FE_LOT_13

FE_LOT_13 alerts “The batch ID does not match the serial number” seems to have arisen from both, improper feeding of batch numbers in to the MVS but also from failed reading of the 2D data matrix by the clients (Figure 14). This explains that the FE_LOT_13 alert type occurred quite randomly and clear patterns behind the reasons was hard to confirm.

7.1.5 NC_PC_02

Serial number is the most important number identifying the single medicine package. NC_PC_02 “unknown serial number” was the reason code for 8 percent of total alerts. The variety within the SNs and PCs among these alert types tells that the root reasons were hard to verify in this alert type. Often the reason behind these was the improper feeding of batch data into the system from behalf of the pharmaceutical company (not all serial numbers of certain batches were fed to the system) (Yrjönen 2020: 16). Considering the drug safety uncertainty in serial numbers should be minimized.

7.1.6 NC_PCK_06

The reasons behind the alert type NC_PCK_06 “Actual pack status doesn't match the undo transaction (set and undo status must be equivalent” were able to identify well. Couple of packages (Figure 15) seems to have been making automatic alerts every 5 minutes at the hospital pharmacies (Figure 16) for several days before automatic verifying has been stopped. Besides these, there has been only a couple of this alert type from pharmacy clients and it seems that the problem had been solved there at the pharmacy at once. This alarm type occurs when undo dispensing function have been used incorrectly (Yrjönen 2020, 22).

7.1.7 NC_PCK_19

Most alerts behind reason code NC_PCK_19 “Property is already set on pack” seems to have arisen from similar cases as the above ones, sending an automatic alert every 5 minutes from hospital pharmacies. 15 percent (111 alerts) of this alert type that came from the pharmacies seemed to be separate and had 96 different Serial numbers involved. These alerts are emerging only if the packages data is not at all in the FiMVS (medicines under compassionate use) (Yrjönen 2020: 18). This means that the pack data is (probably) in the EU Hub, but not in FIMVS.

7.1.8 NC_PCK_22

NC_PCK_22 “pack is already inactive” alerts occurred mostly (74 percent) from pharmacies. Within this alert type, the variety of alerts was big so bringing up one core reason might be hard. Most of these alerts were caused by the users (same end user had already removed the package out of the system). It is also notable that this alert type follows the NC_PCK_23 error. (Yrjönen 2020: 19) As these are the type of alerts that occurred mostly from pharmacies, these are also in concern considering the pharmacists roles dispensing the medicines to the customers. Twenty percent (153 alerts) of the alerts that came from the pharmacies were manually entered (process name “dispense single pack manual entry”) and 98 percent of these (150 alerts) had no Batch ID fed manually.

7.1.9 NC_PCK_23

Errors with reason code NC_PCK_23 “Re-setting of the property via double scan is registered” came also mostly from pharmacies (80 percent) and was mostly (79 percent of the alerts) related to certain seven PCs. NC_PCK_23 formed only 0,3 percent of alerts total. These occurred because the pharmacists had already offset the package. As mentioned earlier that after the data collection period these are no more classified as alerts, only error codes (Yrjönen 2020: 19).

Last alert type NC_PCK_27 “Status change could not be performed“, was reason behind four alerts.

7.2 Interview data

The rather low number of interviews decreases the reliability of the answers but some guidance of how the Pharmacists at pharmacies internalize and interpret the alerting process can be utilized.

7.2.1 Thematic analysis model

The analysing of the results were done following thematic analysis method's phases. Below on the Figure 21 is demonstrated the themes and codes gathered from the interview data. After going through the data, the following were selected as themes: Medical safety, Pace, Instructions and Moods.

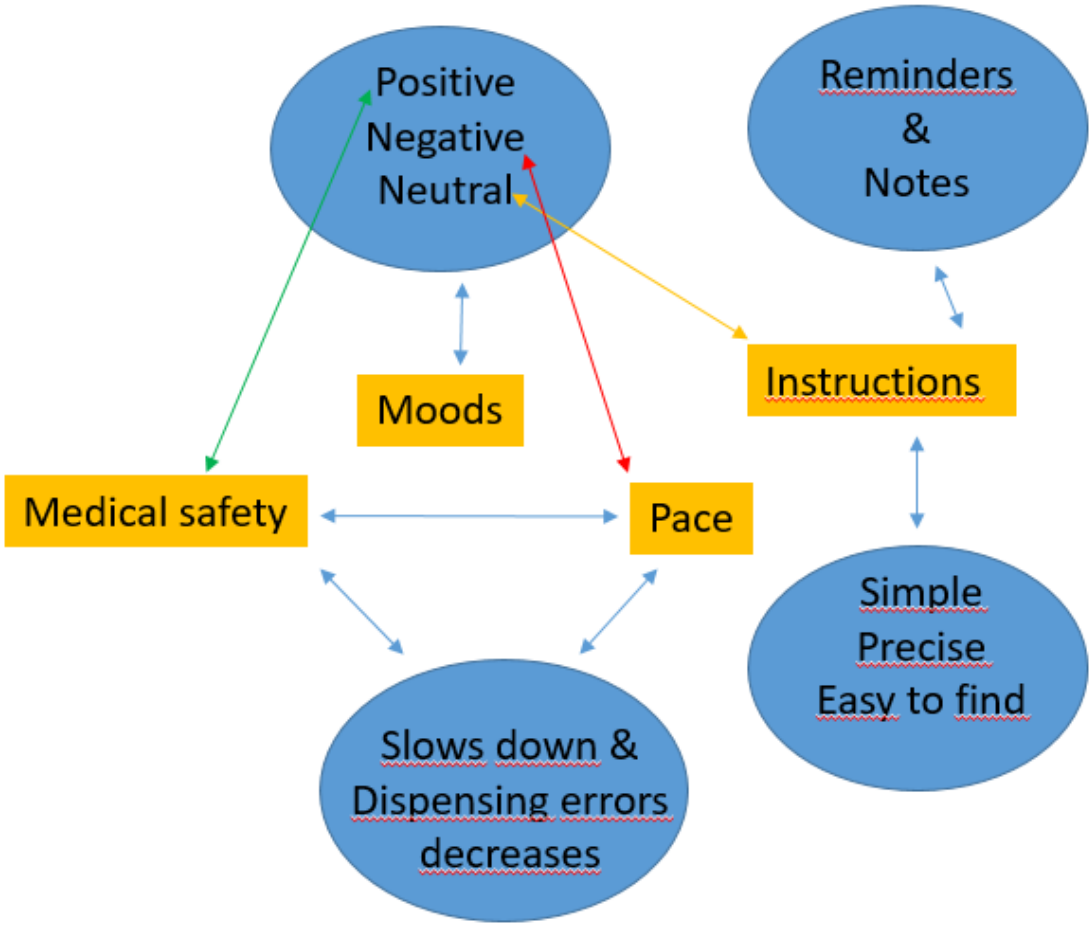

Figure 21. Map of themes and codes

Increased medical safety through verification and the negative "side" effect that it slows the dispensing a bit came hand in hand in the answers so it was natural to choose these as themes. The attitude towards the system seemed to arise different motions among the answers. You could clearly see positive attitudes towards the system from answers

like “Easy, no problems, one routine task among others” and on the opposite, negative answers like “I really do not understand anything about the codes so yes those could be more understandable”. There were also neutral approach in many answers especially on the answer considering instructions. Considering the instructions, pharmacists clearly brought out that reminders and notes from the system is needed and that the common instructions needs to be simple enough, precise and within the reach of hands. The colours of the double-headed arrows describes the moods towards different themes.

These answers tells that there might be a bit uncertainty towards the alarming process of the system from behalf of the pharmacists. Also, the pharmacists will to know more is present. Thematic analysis method helped in analyzing the interview questions so it can be seen as a working method to be used with qualitative analysis.

7.2.2 Interview questions opened

From the answers can be found that the pharmacists perceives that the dispensing have slowed a bit because of the verification (Figure 20). Answerers also pointed out the advantages of the verification of the dispensed medicine, as it allows no space for dispensing errors when successful verification has been made and this way improves medical safety.

Overall pharmacists perceives that their readiness has been in an appropriate level and that their pharmacies have thorough instructions and guidelines. Even though, the pharmacists would like to have more information of the alerts and codes and how to react into an alert.

7.3 Other aspects

Handling such a big changes to pharmacists’ day-to-day routines like dispensing medicines requires good management. According to the answers, the pharmacists tolerate changes quite well and their resistance to change is not that common. Even though the verification effects negatively the customer service with slowing the dispensing (figure

20) it seems that the benefits (no room for dispensing errors or medicine falsifications) of the verification system overruns the negative effect on customer service.

The supply chain among the MVS involves many different stakeholders so it must be managed well. The co-operation of different stakeholders have also improved during the data collection period as for example the expiry date related alerts were able to be lowered with efficiently managing throughout the supply chain. Co-operation of different stakeholders among the supply chain should be among everyone's interest.

The ever-decreasing number of alerts highlights the importance of the soft launch. Variety types of alerts and reasons behind the alerts had occurred which were lowered with efficient process management during the data collection period (for example the expiry date related alerts). Here the process of alerting system was approached with keeping the focus on the root causes of the alerts and keeping the whole picture of the system on mind, not to forget the end-users of the system, the pharmacists. The efficacy of the alerting system and the work of pharmacists have been able to facilitate with streamlining the process and improving the instructions to pharmacists and the pharmaceutical companies during the process. The building up of the FiMVS have involved many risks, for example that the packages could not have been dispensed out of the pharmacy if the system did not operate with sufficient level. These risks have been managed and handled well during the process and medical safety have not suffered from the implementation of the system (Yrjönen 2019: 23).

The pharmacists' answers partly tone with the alerting data. As most of the alerts were related to improper feeding of the data into the system, pharmacists had a little to do with these alerts. However, if taking an example of the alert code: NC_PCK_22 "pack is already inactive", here the pharmacists knowledge could have been better as these were mostly caused by the users. As was mentioned, these represented only a minor amount of total alerts so the issue was not such so often reoccurring. Also, the problems with 2D readers affected the verification. Along with the implementation of the system, these issues have been solved with different parties involved in the process (fixing the 2D readers, updating packaging materials so that the 2D barcode and the linear barcode are not on the same side of the package so that the reader will not mistakenly read both codes at once and set up an alarm). (Yrjönen 2019: 24-25)

The overall knowledge of different parties related to the system could have been shared more thoroughly as for example the packages that had the 2D barcode but was not in the system. These packages could have been identified earlier and information could have been shared that those needed not to be verified. The Figure 19 “Alerts by process name” also shows the alerts with process name “Dispense single pack manual entry”. These were caused by the users but may have been (at least partly) related to the packages that had the 2D barcode but was not in the system. Importance of soft-launch period helped in this issue also a lot and the amount of alerts kept decreasing during the data collection period.

Considering the research questions the study was able to introduce reasons behind the alerts and potentially offer new perspectives on how the alerts could be lowered. Also, what were effective ways to lower the alerts during the data collection period was brought up. Pharmacists’ readiness to work with the system was evaluated and their perceptions summarized.

7.4 Ethical questions

Ethical questions were taken into an account during the research process. Writing of the thesis was done in accordance with good manners avoiding plagiarism and with respect towards the referenced writers. (Roig 2015: 1-4) Mutual Non-disclosure agreement with FiMVO was subscribed and the alerting data treated only by the concept of the thesis and according to the instructions of The European Code of Conduct for Research Integrity. (The European Code of Conduct for Research Integrity 2017: 6). Research questions for the pharmacists were framed so that the questions would not deal with any specific data of the answerer. However, the interviewing data was also treated only by the concept of the thesis and according to the instructions of The European Code of Conduct for Research Integrity (The European Code of Conduct for Research Integrity 2017: 6)

8 Conclusions

Through globalisation and various supply chains involved in the distribution of pharmaceuticals, the falsified medicines have find their way to the legal supply chain of medicines in Finland as well. This emphasizes how important it is that the system is functioning properly and every potential falsification is discovered.

Results and conclusions of the study reveals that the overall performance of the systems alerting process improved during the data collection period. Results shows that the reasons behind the alarms were various and one main reason was hard to define. The system offers keys for better medical safety through the possibly reduced amount of dispensing errors.

Potential development suggestions considering the verification is streamlining of the verification so that it would not be slowing the dispensing. On the other hand, when pharmacists internalize the verification as a part of the dispensing process, it may improve patient safety in the best case when the pharmacists have more time for medication counselling. Better tools and guidelines for the pharmacists in reacting to alerts could be offered.

One option for further studies is to change the approach and focus on the 150 000 (!) successful daily verifications (Yrjönen 2019: 8) and through these figure what has been done right at the beginning and how the system have been build up. Other possible further study is to examine if the dispensing errors have really been reduced and on the other hand, medical safety improved. Also, would be interesting to examine from the patient perspective that whether or not EMVS gives more security on how the patients perceives their medical safety and if it is able to increase the trust towards the legal supply chain of medicines.

9 References

Al-Abri, R. (2007). Managing Change in Healthcare. Oman Med J. 2007 Oct; 22(3): 9–10.

Alteryx (2021). Products- Alteryx Designer. < https://www.alteryx.com/products/alteryx-platform/alteryx-designer> Read 8.5.2021

Bansal, D., Malla, S., Gudala, K. & Tiwari, P. (2012). Anti-Counterfeit Technologies: A Pharmaceutical Industry Perspective. Scientia Pharmaceutica. Open access Review.

Bigdeli, M., Peters, D., Wagner, A. (2014). Medicines in Health Systems: Advancing access, affordability and appropriate use. WHO Library Cataloguing-in-Publication Data.

Braithwaite, J. & Donaldson, L. (2016). Patient Safety & Quality. The Oxford Handbook of Health Care Management (p.325-352). Oxford Handbooks Online, Online Publication Date: Jun 2016.

Braun, V. & Clarke, V. (2006). Using thematic analysis in psychology. Qualitative Research in Psychology. University of the West of England, Bristol, United Kingdom.

Bush, P. & Daniels, R. (2014). Health Care Systems and Transitions of Care: Implication on Interdisciplinary Pharmacy Services. NCMJ vol. 78, no. 3.

Crowe, S., Cresswell, K., Robertson, A., Huby, G., Avery, A., Sheikh, A. (2011). The case study approach. BMC Medical Research Methodology.

Dawson, C. (2002). Practical Research Methods – A user-friendly guide to mastering research.

COMMISSION DELEGATED REGULATION, (EU) 2016/161 of 2 October 2015.
DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. 8 June 2011.

da Silveira e Silva, R., Sznelwar, L, e Silva, V. (2012). The use of participant-observation protocol in an industrial engineering research. Research article. Work, vol. 41, no. Supplement 1, pp. 120-126, 2012.

Dwyer, J. (2014). Change Management for Health Leadership Teams, Technical Brief.

EMVS European Pack Coding Guidelines, Version 4. < https://emvo-medicines.eu/knowledge-database/#11415>. Read 13.4.2021

EMVO Letter of Announcement: Expiry Date Mismatch (2019). < https://www.laakevarmennus.fi/sites/default/files/attachments/0070_EMVO_LoA_20190804_Expiry%20Date%20Mismatch.pdf> Read 11.5.2021.

European Code of Conduct for Research Integrity (2017). Revised edition. Allea – All European Academies. < https://www.allea.org/wp-content/uploads/2017/05/ALLEA-European-Code-of-Conduct-for-Research-Integrity-2017.pdf> Read 7.5.2021

European Medicines Verification System (EMVO) (2019). EMVO's mission <https://emvo-medicines.eu/mission/# > Read 18.7.2019

Fimea (2018), Keuhkosyöpälääkettä koskevaa lääkeväärennöstä selvitetään <https://www.fimea.fi/-/keuhkosyopalaaketta-koskevaa-laakevaarennosta-selvitetaan> Read 7.5.2021

Fimea (2018), Käyttökiellossa olevat Velcade-pakkaukset vahvistuneet väärennöksiksi <https://www.fimea.fi/-/kayttokiellossa-olevat-velcade-pakkaukset-vahvistuneet-vaarennoksiksi> Read 7.5.2021

FiMVO Suomen Lääkevarmennus (2018). Lääkevarmennusjärjestelmä <https://www.laakevarmennus.fi/laakevarmennusjarjestelma> Read 9.12.2018.

FiMVO Suomen Lääkevarmennus (2019). About us. <https://www.laakevarmennus.fi/en/about-us> Read 18.7.2019

FiMVO Suomen Lääkevarmennus (2020). Olemme päivittäneet hälytysohjeistustamme. <https://www.laakevarmennus.fi/sites/default/files/2020-12/NMVO-0049_Alert%20Handling%20Guideline%20for%20Medicines%20Verification%20System%20for%20System%20Users.pdf>. Read. 24.4.2021

FiMVO Suomen Lääkevarmennus (2021). Mistä tunnnistat väärennetyn lääkkeen? Et välttämättä mistään. <https://www.laakevarmennus.fi/mista-tunnistat-vaarennetyn-laakkeen-et-valttamatta-mistaan> Read 25.4.2021.

Green, K., López M., Wysocki, A., Kepner, K., Farnsworth, D., Clark, J. (2002) Revised Oct 2015. Diversity in the Workplace: Benefits, Challenges, and the Required Managerial Tools.

GS1 Company Prefix (2021). < https://www.gs1.org/standards/id-keys/company-prefix> Read. 10.5.2021.

GS1 Healthcare GTIN Allocation Rules Standard (2020). Release 10.0. Ratified June 2020. <https://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf> Read 11.5.2021

Jack, I. & Van Der Vorst, G. (2004) Supply Chain Management: theory and practices.

Kananen, J. (2011). Kvantti: Kvantitatiivisen opinnäytetyön kirjoittamisen käytännön opas. Jyväskylän Ammattikorkeakoulun julkaisuja 118.

Lahtinen, J. & Isoviita, A. (1998). Asiakaspalvelu ja markkinointi. Gummerus Kirjapaino Oy.

Lewis, R. & Fletcher, M. (2005). Implementing a national strategy for patient safety: lessons from the National Health Service in England.

Merks, P., Swieczkowski, D., Byliniak, M., Drozd, M., Krupa, K., Jaguszewski, M., Brindley, D., Naughton, B. (2016). The European Falsified Medicines Directive in Poland: background, implementation and potential recommendations for pharmacists.

Neuman, W.L. (2014). Social Research Methods: Qualitative and Quantitative Approaches (seventh edition). Pearson Education Limited.

Noble, H. & Smith, J. (2015). Issues of validity and reliability in qualitative research. Evidence Based Nursing.

Ozawa, S., Evans, D., Bessias, S., Haynie, D., Yemeke, T., Laing, S., Herrington, J. (2018). Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low- and Middle-Income Countries A Systematic Review and Meta-analysis.

Rasheed, H., Höllein, L., Holzgrabe, U. (2018). Future Information Technology Tools for Fighting Substandard and Falsified Medicines in Low- and Middle-Income Countries.

Receptum (2021). Lääkevarmennus helposti MAXXin loppuinfossa. <https://www.receptum.fi/laakevarmennus-hoituu-maxxin-loppuinfossa/> Read 8.5.2021.

Roig, M. (2015). Avoiding plagiarism, self-plagiarism, and other questionable writing practices: A guide to ethical writing. Second revision.

Santos, C., Santos, V., Tavares, A., Varajão, J. (2014). Project Management success in health – the need of additional research in public health projects.

Sylim, P., Liu, F., Marcelo, A., Fontelo, P. (2018). Blockchain Technology for Detecting Falsified and Substandard Drugs in Distribution: Pharmaceutical Supply Chain Intervention.

Włodarczak, U., Swieczkowski, D., Religioni, U., Jagszewski, M., Krysinski, J., Merks, P. (2017). Awareness of the implementation of the Falsified Medicines Directive among pharmaceutical companies' professionals in the European Economic Area.

Yrjönen, T. (2019). FiMVO: Lääkevarmennusprosessit jakeluketjussa – miten voimme parantaa? <https://www.laakevarmennus.fi/sites/default/files/attachments/L%C3%A4%C3%A4kevarmennusprosessit%20jakeluketjussa%2013062019.pdf> Read 12.5.2021

Yrjönen, T. (2020). FiMVO: SOP –Alert Handling Guideline for Medicines Verification System for System Users. < https://www.laakevarmennus.fi/sites/default/files/2020-12/NMVO-0049_Alert%20Handling%20Guideline%20for%20Medicines%20Verification%20System%20for%20System%20Users.pdf> Read 11.5.2021.

Appendix 1. Interviewed pharmacists

Interview #	Interviewed	Date	Language	Interview type	Duration
1	Pharmacist	15.10.2019	Finnish	Printed questionnaire	
2	Pharmacist	17.10.2019	Finnish	Printed questionnaire	
3	Pharmacist	17.10.2019	Finnish	face-to-face	15 minutes
4	Pharmacist	19.10.2019	Finnish	Printed questionnaire	
5	Pharmacist	11.11.2019	Finnish	email	
6	Pharmacist	27.11.2019	Finnish	email	

Appendix 2. Interview questions

Interview questions

1. “What pharmacy it-software the pharmacy that you are working in is using?”

2. “How have you felt the Verification system have affected your work?”

3. “Is it clear to you what to do when the system makes an alert? What kind of problems have you faced and how have you started solving them?"

4. “Do you feel like you have got enough instructions to react to alerts when it happens?”

5. “What kind of instructions and guidelines would you like to have for the alerts?”

6. “Should the Maxx/Salix/PD3/apteekkariliitto offer better instructions in reacting to alerts at the time of an alert?”

7. “Should the codes of the alerts be opened more so that would help the possibly busy decision during the alert?”

8. “Are you aware, or would you like to be aware, of what is making the alerts? Would you like that the IT-software that you are using tells you that more precisely?”

9. “Any other comments or concerns about the verification system or your role as a pharmacist in it”?