Final Project – Digital Literacy

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Application of 2D Barcode on Pharmaceutical Product Labels in Indonesia to Improve Drug Control

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Abstract

The increase in reports of counterfeit cases in Indonesia makes BPOM as the national food and drug regulatory association must create a surveillance system. 2D Barcode has ability to encode different types of information. Previously, barcodes are widely recognized by end customers as scanning at the point of sale during product purchase. 2D barcode scanning technology uses patterns, shapes and points to encrypt information both horizontally and vertically. 2D barcodes can encrypt more characters in the same space as 1D barcodes. 2D barcodes can have 2,000 or more characters. So that it can store information on the date of production, the name of the manufacturer, the marketing authorization number, or other information that is needed by the community when choosing and using the product. The government has issued regulations regarding the implementation of 2D barcodes in drug and food control through the Regulation of POM No. 33 of 2018. Through this regulation how are the implications of the application of 2D barcodes to fake drug cases in Indonesia.

Keywords: anti-counterfeit, 2D Barcode, QR-Barcode, BPOM

1) Introduction

Health is a human right that has social responsibility. Currently health awareness is increasing. This was accompanied by the addition of drug consumption in Indonesia. Self-medication, which is an independent medical treatment effort without a diagnosis by medical personnel, directly estimates the kind of disease and the drugs given. In an age of technological advancements, online shopping is the choice of the public. They search quickly for the types of drugs needed and quickly the internet will provide information on stores that sell and compare prices provided by these stores so that people do not need to ask one-to-one drug stores or pharmacies that are available (Suherman, H. and Febrina, D., 2018).

However, the business of counterfeit medicines and cosmetics is increasing every year. National Agency of Drug and Food Control of Republic Indonesia or commonly called BPOM found 1,312 counterfeit drug and cosmetic evidence sold online in 2016. However, a year later the number rose by more than 400% to 4,796 evidence (Putra, 2018). Data from the Ministry of Communication and Information Technology Indonesia states that in 2018 the number of internet users in Indonesia will reach 171.76 million or 64.8% of the total population. That number jumped up from 2017 which recorded 143.26 million people and in 2016 recorded 132.7 million people (Informatika, 2018).

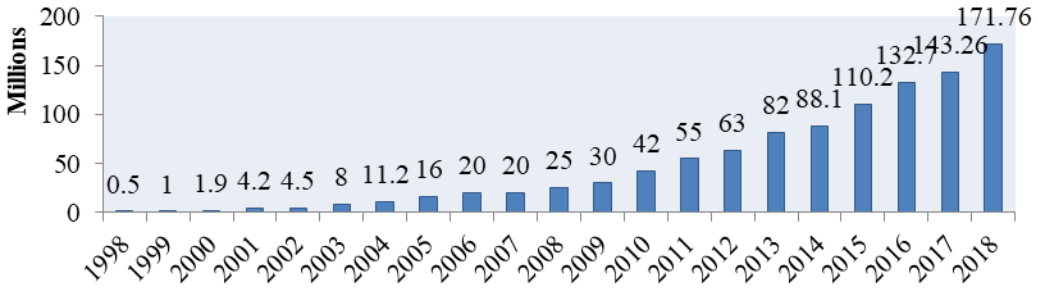

Figure 1. Trend of the number of internet users in Indonesia from 1998 to 2018 (Informatika, 2018)

Counterfeit drugs are defined as any brand name or generic product sold under a product name without proper authorization. This definition also includes products that have been relabelled or repackaged without authorization; most significant to patient health are counterfeits that contain incorrect drug, no drug, improper dose, and/or contaminants. Risks involved with taking a counterfeit drug include unexpected side effects, allergic reactions, and the worsening of medical condition. Counterfeit drug products pose a potentially serious public health concern and can jeopardize the credibility of the entire industry (K. Surabhi, N. Atul, and G. Arun, 2010). WHO noted on its internet pages from 2016 to April 2020, there were 263 products that were falsified by reports from around the worlds (WHO, 2020).

PSI (Pharmaceutical Security Institute) has collected data on counterfeiting, illegal diversion and theft incidents for seventeen consecutive years. The yearly totals for the last five years are shown on the adjacent bar chart.

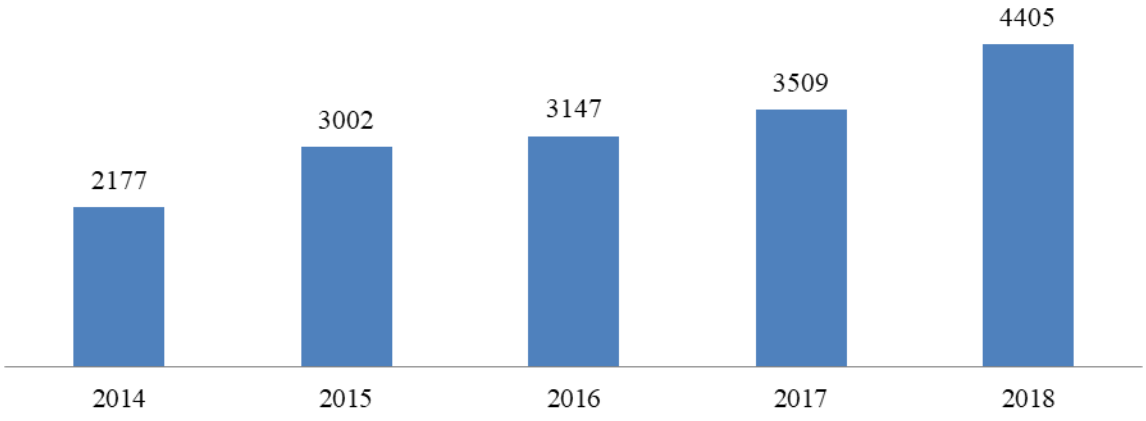

Figure 2. Number of Incident from 2014 until 2018 (PSI, 2019)

The **figure 2** shows 4,405 pharmaceutical crime incidents in 2018, incidents increased by twenty-five percentage (+25%) from 2017, incidents were at an all-time high, and over the past five years, incidents increased by 102%.

Under these conditions, the case of counterfeit products will prevent pharmaceutical traders or pharmaceutical companies in Indonesia from being protected by the products being sold. If there is a product complaint from a customer who consumes the counterfeit product that is listed the trade name or official pharmaceutical company name will damage the company's credibility. Such conditions will make pharmaceutical companies unprotected against their rights as product owners. On the one hand consumers who use these drugs will consume products that are no guaranteed quality, safety and usefulness. The more severe risk is death or chronic illness (Z. Hamid and A. Ramish, 2014). The Indonesian President is also concerned about this condition, as indicated by the issuance of Presidential Instruction (INPRES) No.3 of 2017 concerning increasing the effectiveness of drug and food control. In this paper we will look at what solutions can be done to overcome this problem, especially the use of digital technology that can be done by the government. Based on BPOM (2018) National Agency of Drug and Food Control of Republic Indonesia will adopt 2D barcode results of benchmarking implemented in Iran and Turkey, the implementation of which will be carried out in stages from mid-2019.

2) Literature Review

Stevenson and Busby (2015) argued that there are four main categories of strategies to counterfeit products, namely : (1) extraction strategies; (2) production strategies; (3) distribution strategies; and (4) infiltration strategies. Extraction strategies a strategy whereby counterfeiters obtain products or materials from a legitimate economy. Production strategies a strategy by making counterfeit goods, counterfeiters have facility and technologies to imitate with guinine product. One example of some cases consists of over-production by subcontractors to the original manufacturer. What is done is that the subcontractor company supplies the quantity ordered to the original manufacturer but there are additional production and sales activities under the original manufacturer's trademark without

authorization. In another case, subcontractors make counterfeit products at lower prices and are almost the same, which they consider to be genuine products with genuine manufactured products. Examples of drug counterfeiting activity at the distribution stage are the original drug bundled with counterfeit drugs whose dose calculation is likened to the original product. Distribution activities often occur with market acceptance facilities for counterfeit goods. Other strategies involve legitimate service providers or credible locations or trusted online services. Case in point for infiltration strategies, drugs, traded in parallel markets, where cheaper foreign sales are re-imported and repackaged with local language instructions. This in some cases involves legitimate parts of the supply chain. From this it was found that counterfeit products can actually occur in all parts of the supply chain. Suppliers, producers, wholesalers, small traders and consumers (Stevenson, M. and Busby, J., 2015).

Turkey was the first country to implement a track and trace (T&T) and serialization system which was continued by China. The implementation of this system by Turkey has made cases of fraud or counterfeit products decrease dramatically because there is a government that can communicate both ways with pharmacists about how many units are made and sold, along with the serial number. Track and Trace (T&T) is a system for trace product trips throughout the supply chain, by recording or verifying historical information on location type information. The flow of information in question can be followed both forward and backward (Rotunno, R., et al., 2014). Serialization is the process of changing the data structure or state of an object format that can be saved. Serialization can be in the form of binary serialization, SOAP serialization, and XML serialization. Serialization can be supported with several programming languages such as Ruby, Java, C #, C ++, Objective-C, Python, Smalltalk, .NET families of languages, and PHP (Tauro, C.J.M., et al., 2012). The steps to deal with the problem of product counterfeiting are not enough by making laws or regulations that limit the risk of selling counterfeit products, but there needs to be involvement of the product owner company by

providing a form of packaging that is not easily imitated and giving notice to the existing mass media of the products he has. In addition, customer education needs to be increased so that awareness of potential or introduction to counterfeit products emerges (Thornton, 2018).

2D Barcode

Narayanan, (2012) said QR (Quick Respond) code matrix code system that is developed in Japan by Toyota's subsidiary, Denso Wave, in 1994. The forerunner to the QR Code was created to help track auto parts throughout production area. QR code, also known as fast response, is a two-dimensional barcode that is used to encode information (Krombhloz, K., et al., 2014). The security of 2D barcode is better than 1D barcode. 1D barcode is very easy to read lines and distances formed. However, 2D barcodes are very difficult with the human eye to read the patterns that are formed. 1D barcodes, known as barcode lines can only store 20 numerical digit information. 2D barcodes can store 7,089 numerical digit and 4,296 alphanumeric character , and 1,817 kanji letters as information (Narayanan, 2012).

QR code currently has 40 versions, first version contains 21x21 modules which can store 133 data. Version 40 is a 2D barcode version that has greater data modules, there are 23,648 modules. In **figure 3** is an example of QR code version 2. Following is an explanation of the components of the QR code: (1) *Finder Pattern*, this pattern consists of three distinctive structures and located in the corner of the QR code, except for the lower right. Pattern to activate decoder software recognizes the barcode besides it determines correct orientation; (2) *Separator*, white separator has width one pixel and increase sensitivity other than that as separation from actual data; (3) *Timing pattern*, black and white pattern alternately activates the decoder software as a determinant of the width of the module used; (4) *Alignment Patterns*, this pattern as supporting moderate decoder software for compensation image distortion. The more information the bigger the size of this code and the more alignment of the

pattern added; (5) *Format information*, this section consists of 15 bits located next to separator and save information about the error correction level QR code; (6) *Data*, is mainly where the data stream will be stored in 8 bit code-words ; (7) *Error correction*, is similar part with Data pattern as error correction (8) *Reminder bits*, this part consists of bits that are empty if they cannot be shared to be 8 bit code-words without leftover (Kieseberg, P., et al., 2010).

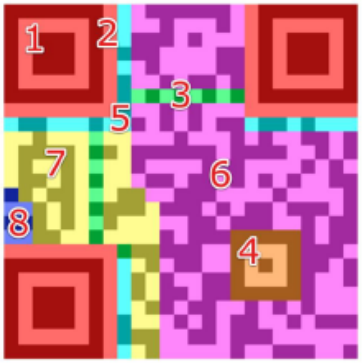

Figure 3. Example QR Code Version 02

Várallyai (2012) explained that the implementation of QR barcodes has been successfully implemented in the agricultural sector to increase productivity. What has been done is to determine the location of planting, monitor the shipping process, provide information to buyers for the location of goods from the seller to the destination, in addition to providing advertising to customers. QR code will require the involvement of the manufacturer. At present QR barcode or 2D barcode is already used in advertising, mobile payments, access control, augmented reality and navigation (Krombhloz, K., et al., 2014).

3) Discussion

Penny Lukito, Head of National Agency of Drug and Food Control of Republic Indonesia or BPOM, explained the BPOM track and trace process flow as shown **figure 4** with following explanation:

1. The first process, as shown in **figure 4**, flow line number 1, the production facility sends data registration number (product information), batch number, expiry date, and serialization. This activity processes 2D barcode requests to BPOM. In this process the hardware requirements needed by the company are computers connected to the internet access to BPOM. At this stage the 2D barcode system or software request is prepared by BPOM.
2. Phase 2 is in accordance with process flow number 2, which is BPOM making 2D Barcodes and sending them to production facilities through software has built by BPOM.

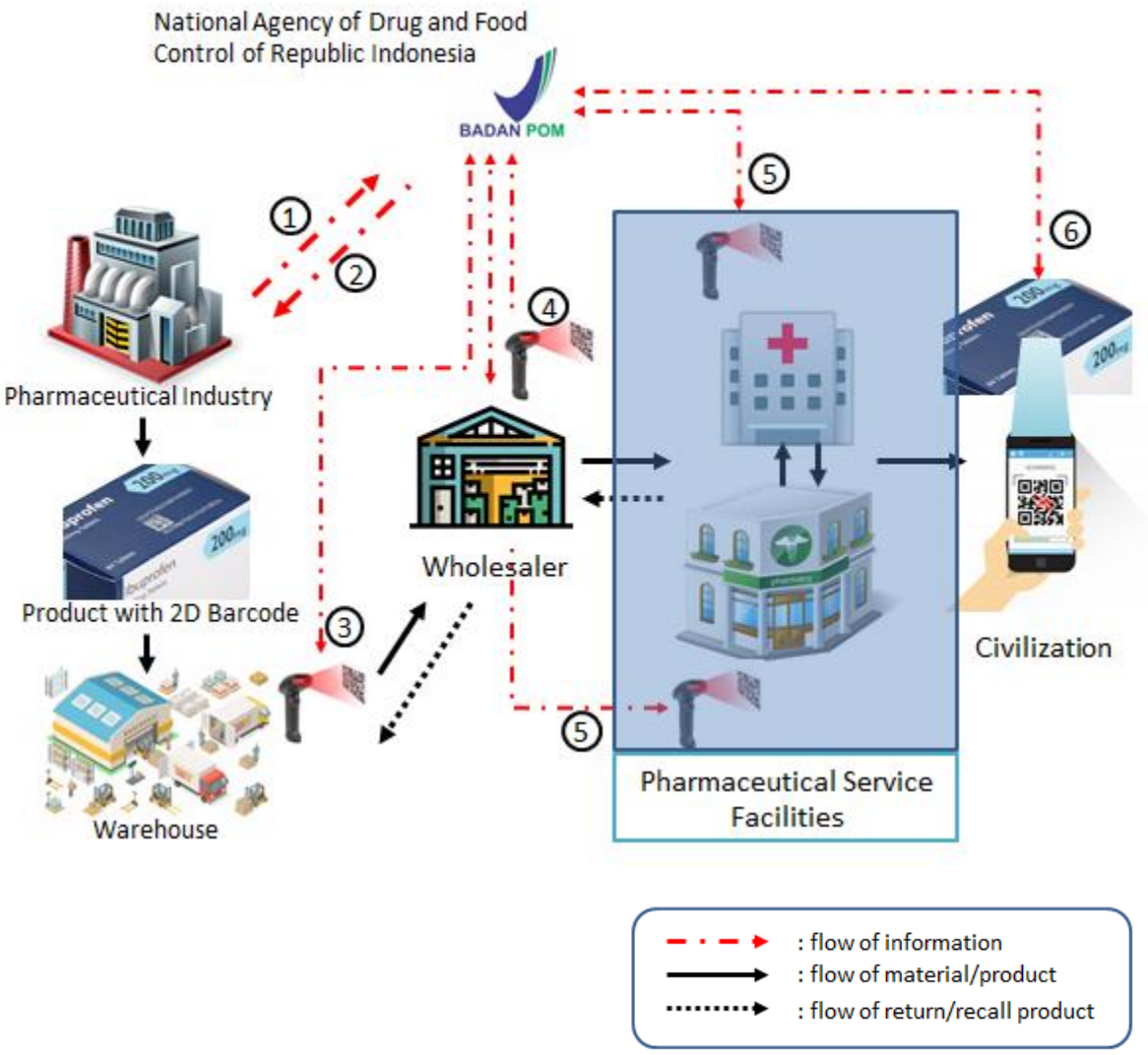

Figure 4. Flow Process of Track and Trace' BPOM System (Lukito, 2017)

After receiving 2D barcode information that is produced, the production facility carries out production and attaches 2D barcode to the packaging according to the system that is already running. Companies must provide and have hardware and software that can communicate with BPOM servers and print product labels / unit boxes. The hardware that a production facility or company must have is: (a) *Server*, to store data sent by BPOM; (b) *Printing / Marking* (PM) (appropriate 2D barcode printer that can be connected to the BPOM system, can read files in the form of CSV or SML sent by BPOM, and can read / translate data generated by BPOM to 2D barcode so that it can be printed on the packaging. Part of this printing consists from print station (print queue), print marking engine, PM mounting, PM delivery / conveyor software, besides this printer / marking needs installation & commissioning; (c) *Verify system* (VS) is a tool and system that checks the eligibility and quality of codes and other information printed by the system, its components are: 2D barcode verification software, text verifier, VS mounting, VS reject / exit delivery, VS installation & commissioning; (d) *Over-wrap station* (OWS) is a system that packs several unit boxes into larger packages, the packaging is designed transparently to facilitate the process of scanning large quantities of products at one time. The components are pack of counter, flipper, clear auto-overwrap film, shrink tunnel, OWS mounting, OWS delivery / conveyor system, OWS installation and commissioning; (e) *Aggregation station* is a system that carries out parent-child relationships. The components are aggregate software and aggregate control station.

3. The third step in **figure 4** process flow 3 is the production facility doing 2D barcode scanning during storage at the warehouse and scanning 2D barcode before sending the product to the production facility. In this stage, the production facility that needs to be prepared is the barcode activation gateway portable barcode activation (scanner). Systems that carry out code activation processes, the pharmaceutical industry must have a product processing system such as ORACLE™, if it is then it can prepare an API (application program interface) for BPOM system

integration. In addition, the system owned by a pharmaceutical industry pharmaceutical company can send data in the form of CSV, SML, other data according to BPOM regulations through an application built by BPOM. It must always be available internet access to the BPOM application for data updates, Scanners in warehouses or warehouses for 2D barcode activation. The scanner must be online or connected to the factory's internal system.

4. Distribution facilities and pharmaceutical service facilities scan products in and out as data recording and sent to BPOM. At the stage in the process flow numbers 4 and 5 in **figure 4**, what is needed is a 2D barcode scanner, which functions to record incoming and outgoing goods (sell) at all facilities by reading the code on the primary / secondary / tertiary packaging and reporting to the BPOM server. Receive in/out/sell gateway, software and portable barcode scanners can send 2D barcode data online information at the facility and the information technology system is capable of sending data in the form of CSV, XML, or other data according to BPOM regulations. In addition, it is necessary to have internet access to the BPOM application for data updates. For distributors and pharmaceutical service facilities that already have a product management system, they can prepare an API (application program interface) for system integration.
5. The last stage in **figure 4** flow process 6 is that people check with a mobile application to find out whether the product purchased is genuine or fake. Mobile apps built by BPOM in the play store and app store. Internet access to the BPOM application, a system for people to verify 2D barcode and public complaints (Lukito, 2017).

Regulation of the Drug and Food Control Agency No. 33 of 2018 (POM, 2018)

In its application, BPOM divided into two systems of application, namely authentication and identification. Authentication is a method of tracing and verifying legality, batch number, expiration, and serial number of medicinal and food products. Meanwhile, identification is a method to verify the legality of drugs and food based on marketing authorization. The application of the authentication

method applies to groups of hard drugs, biological products, narcotics, psychotropic substances. The application of identification methods is aimed at the group of drugs that are included in the class of over-the-counter drugs (drugs with a green circle logo) and limited free drugs (drugs with a blue circle logo), herbal medicines, health supplements, processed foods, and cosmetics.

However, this 2D barcode has limitations. For packaging in the form of strips, blisters, suppositories where the primary packaging at the time of the process is in the form of bulk then there is difficulty in determining the separation as the primary packaging. In addition, the form of packaging such as ampoules or bottles under 10 mL, because of the very small size it is difficult to print 2D barcodes with the size of millimetre.

Information that must be contained in the 2D Barcode authentication methods, includes: (1) distribution permit number; (2) batch number or production code; (3) expiration date; (4) the number of primary codes requested; (5) maximum number of primary codes on secondary packaging; and (6) maximum number of secondary codes on tertiary packaging whereas, in the identification method, the information that must be loaded is only distribution permit number and distribution permit number period. In the regulation, the POM makes exceptions to the condition for medicinal products, traditional medicines, and classes of biological products. However, for food products that have a label surface area of less than or equal to 10 cm^2 (ten square centimetre), they must include a 2D barcode that is given BPOM with a size of at least 0.6 x 0.6 cm.

The public can participate in drug and food control through scanning and reporting the results of the 2D Barcode scan using the BPOM Mobile application. contains information as follows: (1) product name; (2) distribution permit number; (3) the validity period of the distribution permit number; (4)

name and address of the business actor (manufacturing and distribution companies); and (5) packaging.

Track and Trace systems require investment in certain software and applications to existing enterprise IT architecture. It also requires full integration with a centralized system. The system must be able to provide the arrangement and allocation of serial numbers on each packaging production line (Rotunno, R., et al., 2014). Therefore, this will make the ERP system of company adequate interface to servers from global IT in this case the server of BPOM or new T&T system. This track and trace application not only can monitor the distribution and sale of drugs. This system can help companies to reduce business and costs directly or indirectly in the event of recall or returns (Rotunno, R., et al., 2014).

The impact of applying serialization and the track and trace system is that even though data analysis will require a short time interval (the order of milliseconds). However it has an impact on the communication time of different cameras and PLCs. This can cause the working speed of the machine to decrease to allow successful exchange of information so that the impact reduces OEE (overall equipment effectiveness). In addition this system can increase rework activities because the camera reads mismatches (Rotunno, R., et al., 2014).

4) Conclusion

Involvement of all layers, from pharmaceutical industry, pharmaceutical service facilities (hospital, pharmacies, health centre, health offices, etc.), and the communities. The industry makes 2D barcode requests, printing and pasting barcodes on packages, activating via scan / upload CSV files, product shipments. The role of pharmaceutical service facilities is receiving product data through scans, sending products through scans, or incoming and outgoing drug data reported through the application

program interface (API). While the role of the public is to do a 2D barcode scan for product verification and allegedly false product reporting.

Trace and trace and serialization systems are the right solution and have been used successfully by a number of countries for anti-counterfeiting. In addition, this system can assist in product recall, where time and accuracy of reporting are the most important (Moniveena, M.G. and Pramod Kumar, 2017). BPOM as a government institution oversees drug and food sales in Indonesia is appropriate by implementing a track and trace system and serialization system in Indonesia. However, the impact of this change needs to be the readiness of infrastructure in the form of data servers and communication networks that cover all regions of Indonesia. In addition, this will require investment for the private sector or all parties involved in the supply chain to own hardware and software. This needs to be supported by the skills of the personnel or employees they have.

5) Recommendation

The QR barcode activity going forward is not only limited to smartphone, but if in the future Google Glass ™ succeeded in finding Google Glass, it is possible for users using glasses to quickly scan and determine and check products found or seen (Moisoiu, M., et al., 2014).

In this paper only discusses the right and appropriate system for solving problems of counterfeit products by BPOM. From the system that has been explained that there is a relationship between the data system in production facilities, pharmaceutical service facilities, and servers at BPOM. This will pose a risk to data security which will have a systemic impact if there is data piracy. So that the issue of privacy will be important and the handling of the connected data system needs to be sought. In addition, because this system was only implemented in 2018, there has been no study to evaluate its implementation. In the next 5 years there needs to be a study of this implemented system.

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