BJMS
Borneo Journal of Medical Sciences

ORIGINAL ARTICLE

A Cross-Sectional Descriptive Study: Proportion of Authenticity and Complete Product Information of FarmaTag Hologram on Registered Pharmaceutical Products among Selected Mainstream Medicines' Sellers in the State of Sabah (ProvoS)

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Received: 7 September 2023

Accepted: 27 March 2024

Published: 1 May 2024

DOI: https://doi.org/10.51200/bjms.v18i2.5066

Keywords: *FarmaTag hologram, registered pharmaceutical products, authenticity, complete product information, Sabah*

ABSTRACT

FarmaTag Hologram is a two-dimensional QR code sticker that is required on all registered pharmaceutical products (RPP) in Malaysia. By scanning the QR code, the authenticity and product information of the hologram are displayed. However, FarmaTag holograms with incomplete product information may be susceptible to being misused by manufacturers/distributors/suppliers (MDS) for different pharmaceutical products, unregistered pharmaceutical products, or counterfeit products. In addition to misusing, these callous acts may lead to consumer distrust, doubt, and a lack of confidence in the authenticity of RPP. A cross-sectional descriptive study was conducted among Selected Mainstream Medicines' Sellers in the State of Sabah between January 2022 and September 2022 to evaluate the proportion of authenticity and complete product information of FarmaTag Hologram on registered pharmaceutical products (RPP) available among selected Mainstream Medicines' Sellers (MMS) in the state of Sabah. The total sample size was 5048 registered pharmaceutical products. There was no formal sample size calculation performed because this was the first study to explore this topic. All samples being selected from MMS were authentic (100%), which included 31.7% (n = 1600) from

private medical clinics, 18.8% (n = 948), from retail pharmacies, and 49.5% (n = 2500) from Non-Pharmacy Drug Stores (NPDS). However, only 268 (5.3%) samples were found to have complete product information. The findings of this study provide preliminary information to relevant authorities on the authenticity and complete product information of FarmaTag Hologram on registered pharmaceutical products among selected MMS in the state of Sabah.

INTRODUCTION

In Malaysia, all pharmaceutical products must be registered with the Ministry of Health Malaysia (MOH) before they can be sold over the counter or marketed to consumers (Pharmaceutical Services Programme, 2015). Registered pharmaceutical products are guaranteed in terms of Safety, Quality and Efficacy (Pharmaceutical Services Programme, 2015). Based on recorded data, the value of unregistered pharmaceutical products seized from 2012 until 2014 showed an increasing trend (Zulkifli et al., 2016). To combat this issue, in 2005, the Pharmacy Service Program under MOH introduced and launched the usage of a label which was more intricate to copy. This led to the appointment of Mediharta Sdn. Bhd., a Malaysian registered company, came up with the idea of using the Meditag Hologram on all registered pharmaceutical products. The Meditag Hologram has the following features: a) security features such as multi-channel hologram and b) multi-layer security, with overt and semi-covert design aspects. Previously all registered pharmaceutical products only displayed the registration number of the pharmaceutical product (Lancaster, 2006). This was not effective in countering the problems posed for the following reason: the registration number can be easily copied and the public will be in a dilemma in determining the authenticity of pharmaceutical products (Shah et al., 2010).

Since the hologram was introduced, it underwent evolution to combat unregistered pharmaceutical products in the Malaysian market. The usage of Meditag Hologram was implemented and carried out from 2005 until 31st August 2019. On 1st September 2019, it was replaced by FarmaTag Hologram by Techno Secure Print Sdn Bhd (Label Keselamatan Hologram FarmaTagTM, 2021). The FarmaTag Hologram is the latest development of hologram which complies with all MOH safety features (Soal dan jawab, n.d.). This new hologram comes with a matrix bar-code, also known as a two-dimensional bar-code or quick response, QR code, which is a machine-readable optical label that can include data about the object to which it is attached (Hung et al., 2020). With this technology, relevant information about pharmaceutical products can be stored. QR codes are a simple, effective way to distribute information (Czuszynski & Ruminski, 2014). They are quick and convenient for mobile device users (Liu & Liu, 2006; Bate et al., 2011). As mobile devices become more prevalent, this application will make it easier for buyers to authenticate the legality of pharmaceutical products. The QR code on this FarmaTag hologram may be read by the "FarmaChecker" application, which is free to download from the Google Play Store, Apple App Store, or Huawei App Gallery (Shah et al., 2010). Similarly, users can obtain product information for registered pharmaceutical items by scanning the FarmaTag hologram's QR code which is accessible to the public. The legitimacy of the FarmaTag hologram may be easily verified by anyone. The FarmaChecker app allows customers to acquire real-time and quick authentication. When the FarmaTag Hologram is scanned, it displays FarmaTag information such as the serial number, PIN, product maker, product manufacturer or importer, and product information. This application also allows consumers to do instant reporting for unrecognized and/or fake labels detected anytime and anywhere.

However, inadequate product information provided by MDS causes consumer uncertainty as they question whether the product is genuine or not, and

there is a risk of hologram misuse. MDS, for example, may repurpose FarmaTag holograms for other products, such as unregistered pharmaceuticals or counterfeit goods.

Evaluating the authenticity and complete product information of FarmaTag holograms found on registered products is important to help overcome the risk of counterfeit pharmaceutical products. This study is important and beneficial to provide supplementary information regarding the authenticity of the hologram used as well as the completeness of product information provided after scanning the FarmaTag hologram.

Even if similar studies have been completed in other areas of the world, there is still a need to undertake this study in Malaysia, notably in the State of Sabah, due to distinction in terms of system and technological improvements. To the best of our knowledge, no such research has yet been undertaken in Malaysia.

MATERIALS AND METHODS

This was a cross-sectional descriptive study. The study was granted approval by the Medical Research and Ethics Committee (MREC) (22-02874-GMT) registered with the National Medical Research Register (NMMR) and given a registration number NMRR ID-22-02874-GMT. Data was collected from routine inspection of MMS in the state of Sabah from January 2022 until September 2022 as secondary data. The total number of MMS inspected was 1262 premises which included private clinics, private hospitals, private pharmacies and NPDS. The list of 400 private clinics and private hospitals was provided by Cawangan Kawalan Amalan Perubatan Swasta (CKAPS) which included 393 private clinics and seven private hospitals. The list of 237 private pharmacies which have applied for Poison License A in the state of Sabah was obtained from My.Pharma-C system. For NPDS, 625 premises were conveniently selected by Pharmacy Enforcement Branch (PEB) officers during a routine inspection. For private clinics, we excluded veterinary clinics, dental clinics and aesthetic clinics. Furthermore, 'for-cause' inspections of all aesthetic clinics and all NPDS that are currently under investigation by the Sabah Pharmacy Enforcement Branch were excluded from this study as well as they did not undergo routine inspection.

From each Mainstream Medicines' Seller MMS, officers scanned four (4) selected registered pharmaceutical products. So there were 1600 samples from private clinics/ private hospitals, 948 samples from private pharmacies and 2500 samples from NPDS. In conclusion, the total number of registered pharmaceutical products scanned was 5048 samples as seen in Table 1. All 5048 samples were included in the study. Apart from sampling, the officers also investigated other aspects of the MMS to ensure their practices complied with the Malaysian Laws on Poisons and the Sale of Drugs. The FarmaTag Hologram of each selected sample was scanned using the FarmaChecker apps. PEB officers filled a data collection form in Microsoft Excel software 2010. A data collection form, used to collect data related to the objectives of this study, was created. The form consists of the date of inspection, type of MMS premises, number of products scanned, the authenticity of the hologram, and product information.

Data analysis

The IBM SPSS Statistics (Version 28) was used to analyse all data. For both objectives, the results were presented as frequencies and percentages.

Ethics approval

On February 21, 2023, the Malaysia Research Ethics Committee (MREC) of the Ministry of Health reviewed and approved the study under registration number 22-02874-GMT. The principal investigators were the only ones with access to all the data, and they were

Table 1: Census sampling method was carried out for the selection of 5048 samples from 1262 premises of MMS.

MMS		
Private clinics (GP)/ Private Hospitals	**Private pharmacies (Poison License A premises)**	**NPDS**
400 premises	237 premises	625 premises
Total MMS (400 + 237 + 625) = 1262 premises		
FarmaTag Hologram on RPP scanned by FarmaChecker apps		
400x4 =1600	237x4=948	625x4=2500
Total FarmaTag Hologram on RPP scanned (1600 + 948 + 2500) = 5048 samples scanned		

GP: General practitioner

only used for research. The Malaysian Good Clinical Practise Guideline and the Declaration of Helsinki's ethical guidelines were followed when conducting the study.

RESULTS

For the proportion of authentic FarmaTag holograms on registered pharmaceutical products, a total of 5048 samples of registered pharmaceutical products were scanned throughout this study. A summary of the authenticity of the FarmaTag hologram and complete product information on registered pharmaceutical products are seen in Table 2. All samples being selected from MMS were authentic (100%), which includes 31.7% (n=1600) from private medical clinics, 18.8% (n=948) from retail pharmacies and 49.5% (n=2500) from NPDS. However, only 268 (5.3%) samples were found to have complete product information. More than half of the samples (79.8%) were from NPDS and the remaining were from private pharmacies (20.2%) and none from private clinics and private hospitals.

Table 2: The proportion of authentic and complete product information of FarmaTag hologram on RPP..

Variable	Number of MMS scanned for RPP	Number of FarmaTag holograms on RPP scanned	Number of authentic FarmaTag holograms on RPP found in the MMS	Number of complete product information on FarmaTag Holograms found in the MMS
	n (%)	n (%)	n (%)	n (%)
MMR	N = 1262	N = 5048	N = 5048	N = 268
Private medical clinics	400 (31.7%)	1600 (31.7%)	1600 (31.7%)	0 (0.0%)
Private pharmacies	237 (18.8%)	948 (18.8%)	948 (18.8%)	54 (20.2%)
Non-pharmacy drug store	625 (49.5%)	2500 (49.5%)	2500 (49.5%)	214 (79.8%)

DISCUSSION

Ten per cent (10%) of the world's pharmaceuticals have been estimated to be counterfeit (Bate et al., 2011). This global problem is responsible for around one million deaths annually and has a market value of up to $200 Billion (O'Hagan et al., 2018). Pharmaceuticals are vulnerable to counterfeiting due to the high intensity of the pharmaceutical industry and high demand. The data available confirms this. According to the 2019 Organisation for Economic Co-operation and Development/European Union Intellectual Property Office (OECD/EUIPO) report, pharmaceuticals were the 10th most counterfeited product category out of 97 recorded product categories between 2014 and 2016. In 2016, the global trade in counterfeit pharmaceuticals was valued at USD 4.4 billion. This amounts to 0.84% of total global pharmaceutical imports (OECD, 2020). According to the OECD/EUIPO customs seizures database (2019), United States brands were disproportionately affected by the trade in counterfeit pharmaceutical goods from 2014 to 2016. They were followed by the European economies of the United Kingdom, France, Austria, Germany, and Switzerland. This result is not surprising given that the United States, Switzerland, Germany, and France are the world's largest pharmaceutical producers. According to the United Nations Industrial Development Organization's (UNIDO) Industrial Statistics Database, the United States accounted for 37.6% of global pharmaceutical output in 2016, making it the world's leading producer of pharmaceutical products and medicines. It was followed by Switzerland (14%), Germany (8.9%), and France (6.8%) (OECD, 2020).

India, China and some Far East Asian Economies, including Vietnam, Indonesia, Pakistan and the Philippines, appear to be the main producers of counterfeit pharmaceuticals traded worldwide. India remains the primary source economy for counterfeit pharmaceuticals, making up 53% of the total seized value of counterfeit pharmaceutical products and medicines worldwide in 2016 (up from 53% in 2011-2013). It was followed by China (30% in 2014-2016 compared to 33% in 2011-2013), the United Arab Emirates (4% in both periods), and Hong Kong (China) (4% versus 3%) (OECD, 2020).

The Pharmaceutical Association of Malaysia reported in 2005 that 5% of prescription medicines, including eye drops, inhalers, and erectile dysfunction medications, were counterfeit (Stevens & Mydin, 2013). Pfizer conducted a market survey on its innovator drugs (Viagra, Norvasc, and Lipitor) in Malaysia in 2006, which revealed that 4.8% were counterfeited products (Zulkifli et al., 2016). In 2015, the Malaysian Ministry of Health revealed that 5.2% of over-the-counter medicines were counterfeit (Ting et al., 2018).

The goal of this study was to evaluate the proportion of the authentic and complete product information of FarmaTag Hologram on RPP available among selected MMS in the State of Sabah. We used the census sampling method to select all 5048 Farmatag Holograms on RPPs scanned during routine inspections by PEB officers.

We discovered that 100% of the samples had authentic FarmaTag holograms and only 5.3% of these samples had complete product information which was 268 samples. Samples with complete information were found mostly in private pharmacies, 20.2% (54 samples) and NPDS, 79.8% (214 samples). None of these samples were detected in private clinics and private hospitals. These stark differences are due to the majority of the samples with complete product information in the Farmatag Hologram are from over-the-counter and traditional medicines, which are more commonly sold in private pharmacies and NPDS, as opposed to private clinics and private hospitals, which are more focused on providing and selling controlled medicines.

From this data, we found that most of the MDS failed to complete the product information of the FarmaTag hologram on their registered pharmaceutical products. These may be due to a lack of awareness from the MDS on the importance of completing the product information besides no clear and transparency on instruction and regulation from the regulator and enforcement, resulting in MDS takes these things for granted. This is particularly important where counterfeits can pose health hazards.

Limitation of study

Although the proportion of authentic FarmaTag holograms was found to be 100%, this result should be interpreted conservatively. The result should not serve as a sole benchmark to show that the state of Sabah is free from non-authentic FarmaTag holograms. First, this study excluded the premises which had undergone 'for-cause' inspection. Second, the results were subjected to bias as the PEB officer selected the NPDS and samples (registered pharmaceutical products) according to their preferences. Furthermore, due to time constraints during routine inspection, only four (4) samples were selected in each premise regardless of how many registered pharmaceutical products were found in that premise. Moreover, there were possibilities that PEB officers scanned the same products at different premises especially NPDS where less variation of registered pharmaceutical products available could be found. Future study is recommended to use a random sampling method in choosing premises and samples.

CONCLUSION

We discovered that all of the samples had an authentic FarmaTag hologram as a result of this research. Despite this, most of the scanned holograms had insufficient product information. There are risks of MDS having a tendency to recycle authentic holograms on different, unregistered, or counterfeit pharmaceutical products, which is one of the drawbacks of having incomplete product information. As a result, despite the use of authentic holograms, the authenticity and safety of the RPP are called into question. Furthermore, this may cause consumer distrust, doubt, and a lack of confidence in the RPP's authenticity. The findings of this study will be useful in detecting poor product information displayed by MDS, resulting in immediate corrective action. This research could help policymakers implement new policies such as MDS must compulsorily complete product information before their products enter the market. Policymakers can also establish new requirements for the next Hologram company tender. This study can serve as a basis for the next national multi-centre research project. This is important to collect data on the authenticity and complete product information of FarmaTag Hologram on RPP across Malaysia.

CONFLICT OF INTEREST

The authors declared no competing interests.

ACKNOWLEDGEMENTS

The authors would like to express their gratitude to the Director General of Health Malaysia YBhg. Tan Sri Dato' Seri Dr Noor Hisham Bin Abdullah for his approval to publish this manuscript. The authors are obliged to thank the Director of Sabah State Health Department YBhg. Datuk Dr Rose Nani Binti Mudin and Deputy Director of Sabah State Health Department (Pharmacy) Dr Liau Siow Yen for their approval of the data collection of this study and unconditional support in this study. Last but not least, credit to all enumerators from the Sabah Pharmacy Enforcement Branch who devoted their efforts unreservedly in the data collection process to make this study possible.

FUNDING

This study did not receive any specific grant. All the overhead expenses were covered by the

operating fund of the Pharmacy Enforcement Branch, Sabah State Health Department.

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