Investigation of the Reporting System of Schedule-4 Psychotropic Substances in Thailand: A Case Study of Pinazepam

นิพนธ์ต้นฉบับ

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Original Article

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บทคัดย่อ

วัตถุประสงค์: การรั่วไหลของวัตถุออกฤทธิ์ในประเภท 4 ออกนอกระบบควบคุมการกระจายยาเป็นปัญหาที่สำคัญมากแต่ยังไม่มีการวิเคราะห์อย่างชัดเจน การศึกษานี้จึงมุ่งตรวจสอบระบบรายงานและการสอบทานข้อมูลการซื้อ-ขายวัตถุออกฤทธิ์ฯ โดยใช้พินาซีแพมเป็นกรณีศึกษา **วิธีการศึกษา:** เป็นการศึกษาแบบภาคตัดขวางที่ใช้การตรวจสอบรายงานแบบเอกสารและแบบออนไลน์ของพินาซีแพมซึ่งส่งมาที่สำนักงานคณะกรรมการอาหารและยาตั้งแต่ปี 2557 – 2558 รายงานเหล่านี้ได้รับจากผู้ผลิต ผู้นำเข้า ผู้แทนจำหน่าย สถานพยาบาลและร้านยาต่างๆ ข้อมูลปริมาณการซื้อ-ขายในแต่ละระดับของการกระจายยาจะได้รับวิเคราะห์เปรียบเทียบและรายงานโดยใช้สถิติเชิงพรรณนาคือความถี่และร้อยละ **ผลการศึกษา**: ในปี 2557 ประเทศไทยมีการนำเข้าวัตถุดิบพินาซีแพม 40 กิโลกรัม โดยขออนุญาตผลิตเพื่อใช้ในประเทศ 15 กิโลกรัมและผลิตเพื่อส่งออก 25 กิโลกรัม ในการผลิตพินาซีแพมสำเร็จรูปเพื่อใช้ในประเทศ 7 รุ่นการผลิต ผลิตได้จริง 2,639,500 แคปซูล (ร้อยละที่ผลิตได้ 94.27) หลังจากนั้นผู้ผลิตและผู้แทนจำหน่ายขายพินาซีแพมไปทั้งสิ้น 1,990,000 แคปซูลให้กับสถานพยาบาลและร้านขายยา 168 แห่ง คงเหลือในคลังสินค้า 649,500 แคปซูล (ณ วันที่ 31 กรกฎาคม 2558) มีเพียงสถานพยาบาลและร้านขายยา 64 แห่ง (ร้อยละ 38.10) ส่งรายงานแบบเอกสารมายังสำนักงานคณะกรรมการอาหารและยา (อย.) จึงทำให้ไม่สามารถตรวจสอบการกระจายยาไปยังผู้บริโภคได้ **สรุป:** ยังไม่พบการรั่วไหลออกนอกระบบควบคุมการกระจายยาพินาซีแพมตั้งแต่การนำเข้าวัตถุดิบ ผลิต ส่งออกและขายไปยังสถานพยาบาลและร้านขายยาสามารถ แต่ยังไม่สามารถยืนยันการกระจายยาจากสถานพยาบาลไปยังผู้บริโภคได้ ควรมีการเพิ่มพนักงานเจ้าหน้าที่เพื่อตรวจสอบระบบรายงานและการปรับปรุงระบบรายงานออนไลน์ให้รองรับการรายงานให้สมบูรณ์มากยิ่งขึ้น

คำสำคัญ: ระบบรายงาน, วัตถุออกฤทธิ์ในประเภท 4, พินาซีแพม

Abstract

Objectives: The leakage of schedule-4 psychotropic substances from the formal distribution channel is a crucial problem but still unexplored. This study aimed to investigate the reporting system of the substances using pinazepam as a study drug. **Method:** In this cross-sectional study, we investigated the reports both in paper-based and online formats submitted to the FDA during 2014 – 2015. These reports were obtained from manufacturers, importers, distributors, healthcare facilities and drugstores. Data of purchase and sale volume at each step of distribution were compared and reported as descriptive statistics, i.e. frequencies and percentages. **Results**: In 2014, 40 kg of pinazepam was imported to Thailand, i.e. 15 kg being permitted to manufacture finished product for domestic use and 25 kg for exportation. Seven batches of the finished products for domestic use were produced with a capacity of 2,639,500 capsules (or 94.27% actual yield). After the sale of 1,990,000 capsules to 168 healthcare facilities and drugstores combined, 649,500 capsules were left in the inventory of the manufacturers and distributors (as of July 31, 2015). As only 64 healthcare facilities and drugstores (38.10%) submitted the reports to the FDA, the distribution to the consumers could not be examined. **Conclusion:** There was no leakage of pinazepam in the distribution from the manufacturers to the healthcare facilities and drugstores. However, the distribution to the consumers could not be verified. It is recommended that more officers should be allocated to the data verification task and a more comprehensive online reporting system should be in place.

Keywords: reporting system, schedule-4 psychotropic substances, pinazepam

Introduction

The abuse of psychotropic substances causes not only physical and mental, but societal problems as well. Such societal negative impacts included the epidemic of psychotropic substance abuse and criminals affecting safety of other people's life and asset. These problems have called for a tight control on the psychotropic substances. Despite their abuse potentials, many psychotropic substances are medically useful. Benzodiazepines, such as diazepam and pinezepam, have been widely known as effective anxiolytic agents. This dilemma has led many countries to issue laws and regulations to control the use of these psychotropic drugs under the Convention on Psychotropic Substances (1971) of the United Nations Office on Drugs and Crime.[1] In Thailand, the control of psychotropic drugs with abuse potential has been under the provision of the Psychotropic Substances Act, B.E. 2518 (A.D. 1975).

The abuse of psychotropic drugs has been found in various countries. In the US, the death of benzodiazepine overdose had been rising continuously from 1,500 cases in 2001 to 7,500 cases in 2014, a five-fold increase.[2] In the UK, 342 cases of benzodiazepine-related death in 2013 was higher than that in 2012 by 20%.[3] In Thailand, the abuse has been found in various groups of substances including opioids (eg. buprenorphine), sedatives and hypnotics (eg. pinazepam), and stimulants (eg. phentermine).[4] There has been an increasing trend of cases of illegal drug use from 2002 to 2011. The most found cases of illicit use were transquilizer related which increased from 346 cases in 2002 to 719 cases in 2011. With such a high demand, these substances have been illicitly sold widely and the sales were arrested the most.

Thai Food and Drug Administration has established a reporting system for each single step of the distribution of psychotropic substances, especially those in schedule-4, from importation, manufacturing, selling, and exportation. A good reporting system should allow for 1) immediate documentation of purchase and sale data and 2) easy correction and verification of the data. Verification process should be able to compare data from all steps from importation, manufacturing, exportation and distribution to healthcare facilities and drugstores. In other words, volume of imported substances should completely agree with the expected volume of the finished product. For example, for one gram of the psychotropic substance raw material imported, the manufacturer should be able to produce 100 tablets of the finished product of 10 mg tablets, and report to the FDA accordingly. Subsequently, for the sale of 100 tablets of the finished product from the manufacturer or a distributor to a healthcare facility, such purchase volume of 100 tablets should be reported by the healthcare facility to the FDA. In addition, the accumulated volume of sale/dispensing of the finished product at the healthcare facility should also be reported to the FDA. Numbers from all of these distribution steps should agree with each other. Any discrepancy about the number of psychotropic substances and their finished products could potentially indicate a leakage or illicit distribution.

The reporting system should also allow for an effective alarming system once there is a discrepancy or imbalance between purchase and sale data of the schedule-4 psychotropic substances, or when the purchase volume exceeds the amount allowed. Despite a strict control on psychotropic substances with an existing reporting system, the problems of illicit distribution and access of psychotropic substances are still prevalent and have been continuously increasing. With such ongoing problems, this present study aimed to investigate the performance of the reporting system and the data verification process of schedule-4 psychotropic substances under the provision of Thai FDA using pinazepam as a case study drug. The information learned could be useful in improving the control system to alleviate the illicit distribution and access, and subsequently the abuse of these schedule-4 psychotropic substances.

Methods

In this cross-sectional study, reports of pinazepam by manufacturers, importers and distributors were investigated. Reports both in paper-based and electronic forms from 2014 to 2015 were examined. Pinezepam was chosen as the study drug since it was one of the widely used psychotropic substance. Since it is a benzodiazepine, pinazepam has a central nervous system suppression action. It provides anxiolytic, sedative, anti-epileptic and muscle relaxing effects. In addition, pinazepam also causes amnesia or loss of memory. All of these effects of pinazepam suggest a relatively high potential for abuse. In addition, the number of manufacturers and distributors had been known to be limited, hence a high feasibility to complete the study in a reasonable period of time.

Definitions

In this study, licensees of psychotropic substances and finished products included importers, manufacturers, distributors, exporters, healthcare facilities and drugstores. Healthcare facilities included public and private hospitals, clinics, dental clinics, and veterinary hospital and clinics. The importers could be those that imported raw materials and/or finished products of psychotropic substances. The importers could sell raw materials to manufacturers and the finished product to distributors or directly to healthcare facilities and drugstores. The possession of psychotropic substances or their finished products in the healthcare facilities were licensed through either their practicing medical doctors, dentists, or veterinarians. The law mandated that healthcare facilities possessing more than 5 grams of the substance or

10,000 capsules/tablets of the finished product must have the license.

Data collection procedure

Data were extracted from reports, relevant documents and literature. Three steps of investigation were as follows. In **step one**, the situation study, we explored the existing reporting system of the schedule-4 psychotropic substances in Thailand. All involved parties and their relevant responsibilities in reporting system were identified.

Step two was the comparisons of the control of psychotropic substances by means of reporting system among countries. Specifically we compared and contrasted the situations in Thailand and the US. Online reporting system of the two countries was also compared.

In **step three**, we examined the performance of the existing reporting system using pinazepam as the study drug. From all identified steps of reporting system verification process of the Thai FDA, we verified extent and balance of volume of import and export, manufacturing, and sale/dispensing of pinazepam raw materials and finished products at relevant steps of distribution.

Specifically we investigated the amount of distributed pinazepam in the year 2014. Import reports were from the Pre-marketing Control Unit while sale reports were from the Post-marketing Control Unit, Narcotics Control Division, Thai Food and Drug Administration. Volume of imports was taken from the application forms for import of psychotropic substances and the import summary reports of psychotropic substances both in paper-based and online format. For the volumes of manufacturing and sale of pinazepam finished products, data were taken from manufacturing reports and sale reports both in paper-based and online format available from 2014 to July 31, 2015 from the Post-marketing Control Unit.

These data were used to verify correctness and timeliness of the import and manufacturing volumes of pinazepam, and sale volume of the pinazepam finished product. Cross-examination of data from relevant distribution steps both in paper-based and online format was performed. These data included import volume of pinazepam, manufacturing volume of the finished product, volume of sale to distributors, volume of sale to healthcare facilities and drugstores. The data also included purchase and dispensing/sale volume of pinazepam finished product at the healthcare facilities and drugstores.

In terms of data at the level of healthcare facilities and drugstores, reports of purchase and dispensing/sale volume of pinazepam finished products were taken from monthly reports (Psychotropic Substance Form 9). These data were used to verify correctness and timeliness of the purchase and dispensing/sale volume of pinazepam finished products.

This study was approved by the Ethics Committee, Faculty of Pharmacy, Silpakorn University on April 9th, 2015.

Results

Situation of reporting system of the schedule-4 psychotropic substances

Based on the existing reporting system, licensees of psychotropic substances were subject to keeping the relevant reports at their venues. All licensees were mandated to submit all relevant reports to the FDA monthly and annually. Specifically, importers, manufacturers, distributors and exporters were subject to mandatory submission of purchase and sale activities monthly by paper-based report. They were also asked for cooperation to report such activities via online submission. On the other hand, healthcare facilities and drugstores were requested only to submit the report in paper-based format.

The mandatory reports for each of the licensees were as follows. For **importers** of psychotropic substances or finished products, they were required by law to document individual importation activities of psychotropic substances or finished products in Psychotropic Substance Form 6, and individual sale activities of psychotropic substances or finished products in Psychotropic Substance Form 3. Since they functioned as logbooks of activities, Form 6 and Form 3 were kept at the importer's venue. The importers were required to submit a monthly report called Psychotropic Substance Form 9 and an annual report called Psychotropic Substance Form 10. An example of information in Form 9 detailing pinazepam raw material balance was as follows. In a given month, with a total import volume of three kilograms, a total sale volume of two kilograms, and a volume brought forward from last month of one kilogram, it would result in a balance of two kilograms of pinazepam raw material. The annual report (Form 10) was a compilation of data from each month as documented in the monthly report (Form 9) and

the annual summary. In addition to these paper-based reports of Form 9 and Form 10, the importers were also asked for cooperation to submit the two reports online.

For **manufacturers** of psychotropic finished products, they were required by law to document raw material stock balance (Psychotropic Substance Form 1), manufacturing report of volume of theoretical and actual yields (Psychotropic Substance Form 2), individual sale activities of finished product (Psychotropic Substance Form 3), and individual export activities of finished product (Psychotropic Substance Form 7). They were also required to submit the monthly report (Form 9) and annual report (Form 10) similar to those previously described. In addition to these paper-based reports of Form 9 and Form 10, the manufacturers were also asked for cooperation to submit the two reports online like the importers.

An example of information in Form 9 detailing the balance of pinazepam raw material and finished product as documented by a manufacturer was as follows. In a given month, with a total purchase volume of one kilogram of pinazepam raw material, and a volume brought forward from last month of one kilogram, it would result in a balance of two kilograms of pinazepam raw material. To manufacture all raw material into the finished product, these two kilograms of pinazepam would result in a theoretical yield of 400,000 capsules of pinazepam finished product. However, an actual yield of 400,200 capsules was achieved. With a volume brought forward from last month of 50,000 capsules of pinazepam, it would result in a balance of 450,200 capsules. With a total sale volume of 250,000 capsules and a total export volume of 200,000 capsules, it would result in a balance of 200 capsules of pinazepam finished product for the given month.

For **distributors** of psychotropic finished products, they were required by law to document individual export activities of finished product (Psychotropic Substance Form 7) (if any). They were also required to submit the monthly report (Form 9) and annual report (Form 10) similar to those previously described. In addition to these paper-based reports of Form 9 and Form 10, the manufacturers were also asked for cooperation to submit the two reports online like the importers.

For **healthcare facilities** with the license for psychotropic substance possession, they were required to document the balance between purchase and dispensing/sale volume of psychotropic substance finished product (Form 8). This Form 8 recorded names of individual patients who were prescribed the finished product for. Healthcare facilities were required to submit the paper-based monthly report (Form 9) and annual report (Form 10) similar to those previously described. However, they were not asked for cooperation to submit the two reports online.

Lastly, **drugstores** with schedule-4 psychotropic substance possession were required to document individual purchase activities (Psychotropic Substance Form 4) and dispensing of psychotropic substance finished product by prescription (Form 5). They were also required to submit the paper-based monthly report (Form 9) and annual report (Form 10) similar to those previously described. Like healthcare facilities, they were not asked for cooperation to submit the two reports online. The control of psychotropic substances in Thailand via reporting system is depicted in figure 1.

From these findings, the control of psychotropic substance via reporting system in Thailand regulated all steps of distribution from the import of raw material to the name of the patient using the finished product as the end user documented in Form 8. However, one defective step was that some healthcare facilities did not have a license for possession permission of the schedule-4 psychotropic substance. This was because the law only mandated those healthcare facilities that possessed more than 5 grams of the substance or 10,000 capsules/tablets of the finished product to have the license. It was likely that a certain number of these facilities were allowed to possess the substances with no license required. To verify which healthcare facilities were or were not subject to holding a license, an on-site inspection was needed. With a limited number of officers at the FDA headquarter and the nation-wide provincial public health administration offices, this task was mostly incomplete. Therefore, there could be a certain, yet unknown, portion of missing report of the distributed psychotropic substance.

Since healthcare facilities and drugstores were required to submit only paper-based report, not the online version. Verification of the purchase-sale data between manufacturer/ distributor and healthcare facilities/drugstores in the paper-based reports was time consuming and labor intensive. The limited number of FDA officers was evidently a hindrance for this task.

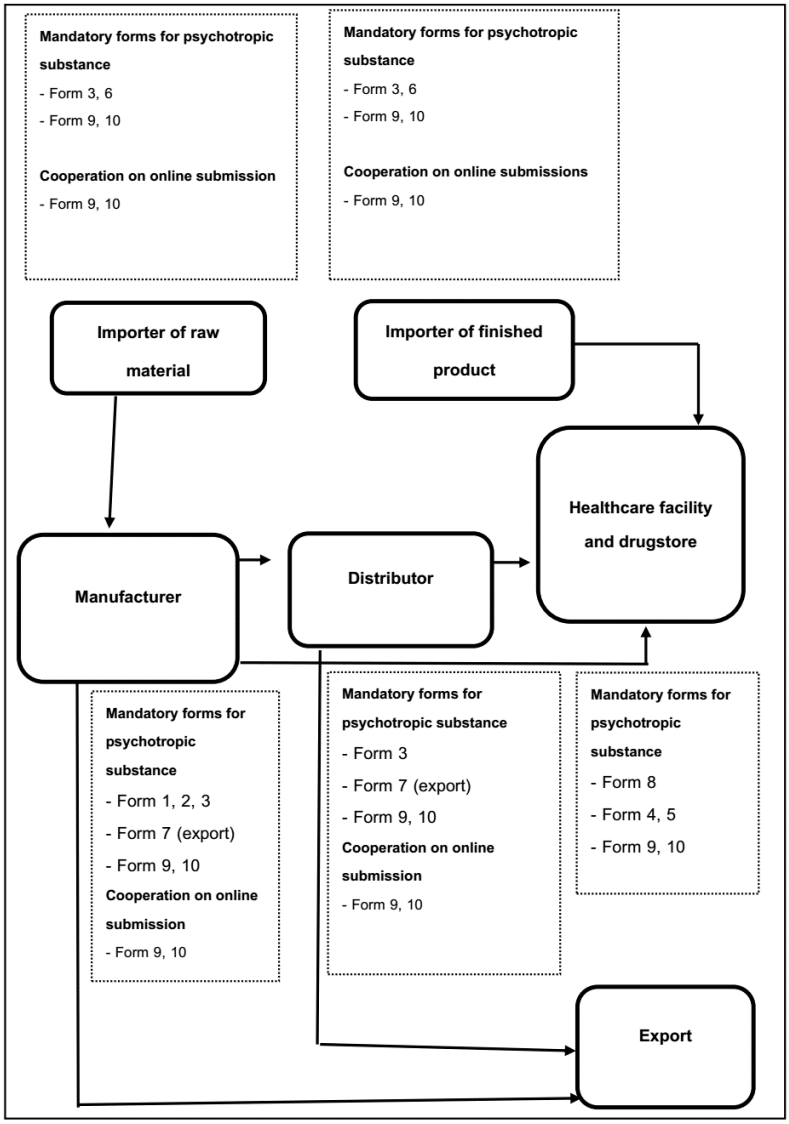

Figure 1 The control of schedule-4 psychotropic substances in Thailand via reporting system as of July 2015.

Note: Forms relevant to each specific licensee.

Form 1 = stock balance of psychotropic substance raw material (for manufacturer)

Form 2 = volume of theoretical and actual yields of psychotropic substance (for manufacturer)

Form 3 = sale activities of psychotropic substances or their finished products (for importer, distributor and manufacturer)

Form 4 = individual purchase activities of psychotropic substance finished product (for drugstore)

Form 5 = dispensing activities of psychotropic substance finished product by prescription (for drugstore)

Form 6 = import activities of psychotropic substances or their finished products (for importer)

Form 7 = individual export activities of psychotropic substance finished product (for manufacturer and distributor)

Form 8 = balance between purchase and dispensing/sale volume of psychotropic substance finished product (for healthcare facility)

Form 9 = monthly summary report of all activities relevant to the given licensee

Form 10 = annual summary report of all activities relevant to the given licensee

The comparisons of the control of psychotropic substances by means of reporting system of Thailand and the US

The control of narcotics and psychotropic substances via reporting system in the US was different from Thailand. With the electronic system called Controlled Substances Ordering System or CSOS[5], prospective purchaser had to register with the Drug Enforcement Administration or DEA for certification. The certificated purchaser then submitted the electronic purchase order to the wholesaler or supplier via specific software. The wholesaler or supplier then verified the certificated purchaser with the DEA. Once approved, the

product of controlled substance was supplied to the purchaser. Once the sale transaction was completed, the wholesaler or supplier had to electronically submit the transaction report to the DEA within 2 working days (Figure 2).

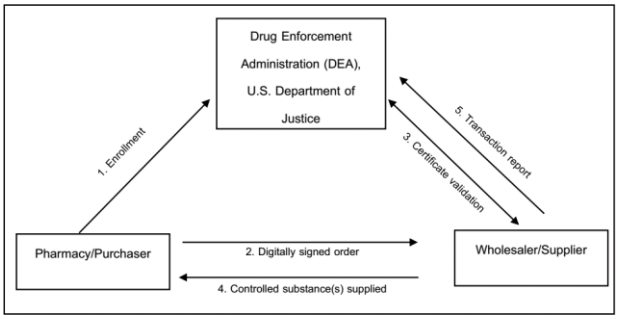

Figure 2 The ordering system for schedule I-IV controlled substances through the electronic transmission system called Controlled Substances Ordering System (CSOS)[5] of the U.S.

The reporting system of dispensing psychotropic substances for the patients at healthcare facilities and drugstores in Thailand was different from that in the US. With the use of electronic prescribing system called E-Prescribing[6], the reporting system in the US seemed to be more comprehensive (Figure 3). This E-Prescribing was controlled by the U.S. Department of Health and Human Services. Under the online E-Prescribing system, once the physician prescribed a schedule-4 controlled substance for a patient, the system transmitted the patient's information the transaction hub which further transmitted the information to the pharmacy benefits manager (PBM) for verification. Once the patient was verified, the information was transferred back to the prescribing physician via transaction hub. If the physician decided to proceed and complete the prescribing process, the prescription order was transmitted to the pharmacy. Once the controlled substance was dispensed to the patient, the purchase and sale transaction was completed.

Evidently, under the online E-Prescribing system of the US, the physician who prescribed, the patient who used and the pharmacist who dispensed the controlled substance could be correctly identified in a timely fashion. Dispensing pharmacists were required to submit the monthly transaction report to the Drug Enforcement Administration (DEA) within the 15th day of the next month. From Figure 2 of which the data of controlled substances distribution from importation, manufacturing, and purchase/sale to the pharmacy in the US were depicted, the information from this online E-prescribing system helped complete the data of substance distribution to the patient as the end user.

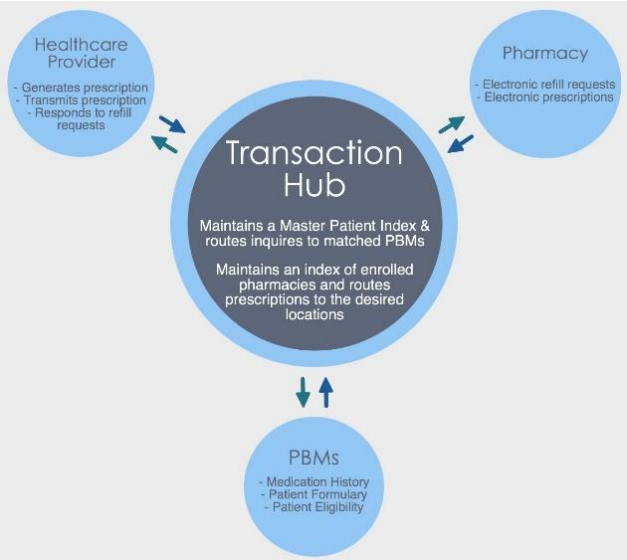

Figure 3 Prescribing system based on the E-Prescribing of the US.[6]

In Thailand, we found that the online reporting system to control the distribution of schedule-4 psychotropic substance was defective. Data from different forms were not linked to offer a practical verification of the volume of the manufacturing and purchase-sale at each of individual transactions. The data of Forms 9 and 10 in the online format were incomplete since the wholesaler/supplier side (i.e., importers, manufacturers and distributors) was only asked for cooperation. Even worse, healthcare facilities and drugstores were not asked for cooperation to submit any data online. Verification of these data was then dependent heavily on manual checks. As a result, the FDA performance on this task was low since their workforce was limited.

The performance of the existing reporting system using pinazepam as the study drug

It was found that only one finished product of pinazepam 5 milligram capsule was registered by one registered manufacturer and one registered distributor. On its green-white capsule, the product brand name, active ingredient name with the number of "5" indicating the strength of the pinazepam finished product were imprinted. The manufacturer registration record of the product was

complete. The submission of the online report of the manufacturer and the distributor was also complete.

It was found that in the year of 2014, a total of 40 kilograms of pinazepam raw material was imported by the manufacturer. The amount the manufacturer filed for permission to import the raw material at the Pre-marketing Control Unit agreed with the imported amount found at the Post-marketing Unit of the FDA. The number that the Post-marketing Unit received was verified by the Bureau of Import and Export Inspection, FDA. The researcher verified the agreement of the data between different sources using the paper-based reports since the data based on the online reporting system of the FDA (i.e., E-logistics) were incomplete.

Of these 40 kilograms of imported pinazepam raw material, 15 kilograms were for filed for domestic use and the rest 25 kilograms were for exportation. Of the 25 kilograms with permission for exportation, 12.90 kilograms were manufactured to a total actual yield of 2,211,900 capsules of 5 mg pinazepam with 12.10 kilograms of pinazepam raw material brought forward to the next year inventory. The manufacturer exported the finished products to Singapore, Hong Kong and the Netherlands. Since the data of sale number to these countries were incomplete in the online report, all data verifications were done based on paper-based reports.

In terms of domestic use, the researcher investigated the manufacture from January 1st, 2014 (the year with the permission to import the 40 kilograms of pinazepam previously described) to July 31st, 2015 (the time before the next permission to import was granted). The manufacturer used all the 15 kilograms to produce 7 batches of finished products for domestic use. The theoretical yield was 2,800,000 capsules of 5 milligram pinazepam. With an actual yield of 2,639,500 capsules, a 94.27% actual production was a result. Based on the monthly report (Form 9) from the manufacturer and distributor, pinazepam finished products were sold to 168 healthcare facilities and drugstores combined. The first batch was sold since April 2014.

The researchers found that from April 2014 to the end of July 2015, a total 1,990,000 capsules had been sold within one year and four months with 649,500 capsules left in the manufacturer inventory as expected. Based on the report of the annual on-site inspection of psychotropic substances by the FDA officers, there were 649,500 capsules left in the inventory. This number was in agreement with the manufacturer report to the FDA.

In terms of healthcare facilities and drugstores, we investigated their reports (Form 9 and Form 10) to the FDA. All reports were only in paper-based format as required by the FDA. No online reports as asked for cooperation by the FDA were submitted. With a limited workforce of the FDA to facilitate our inspection, we spent almost one month to verify these distribution reports submitted by all healthcare facilities and drugstores. The officers were responsible for various tasks other than maintaining the database of these reports. Therefore, their help was definitely limited. Since the data verification was done mostly on paper-based reports, not the electronic ones, our task was highly time-consuming. We found that of the 168 healthcare facilities and drugstores combined to which the manufacturer and distributor sold the finished product, only 64 (38.10%) submitted the monthly report (Form 9) while the rest 104 of them (61.90%) did not (Figure 4).

Ultimately, all findings led to the conclusion that there was no leakage of pinazepam from the importation to manufacturing, exportation, and sale to healthcare facilities and drugstores. However, the distribution from healthcare facilities and drugstores to the patient as the end user could not be fully verified. On-site inspection by the FDA officers was highly needed.

Discussions and Conclusion

In this cross-sectional study, the main findings could be concluded as follows. First, the online reporting system could not verify the agreement between the volume of raw material permitted for importation and the actual import volume. Based on the E-Logistics system, the permitted volume data available from the Pre-marketing Control Unit could not be linked with the data of the actual import volume in the monthly report (Form 9) of which the manufacturer submitted to the Post-marketing Control Unit. The volume numbers from the two reports were incomplete, therefore the agreement verification of the two import numbers could not be done. In terms of exportation, there was a leakage of the finished product based on the online E-logistics report. More export volume data had to be obtained from the monthly report (Form 9). Finally the agreement of the export volume of pinazepam finished product at each relevant distribution step was found.

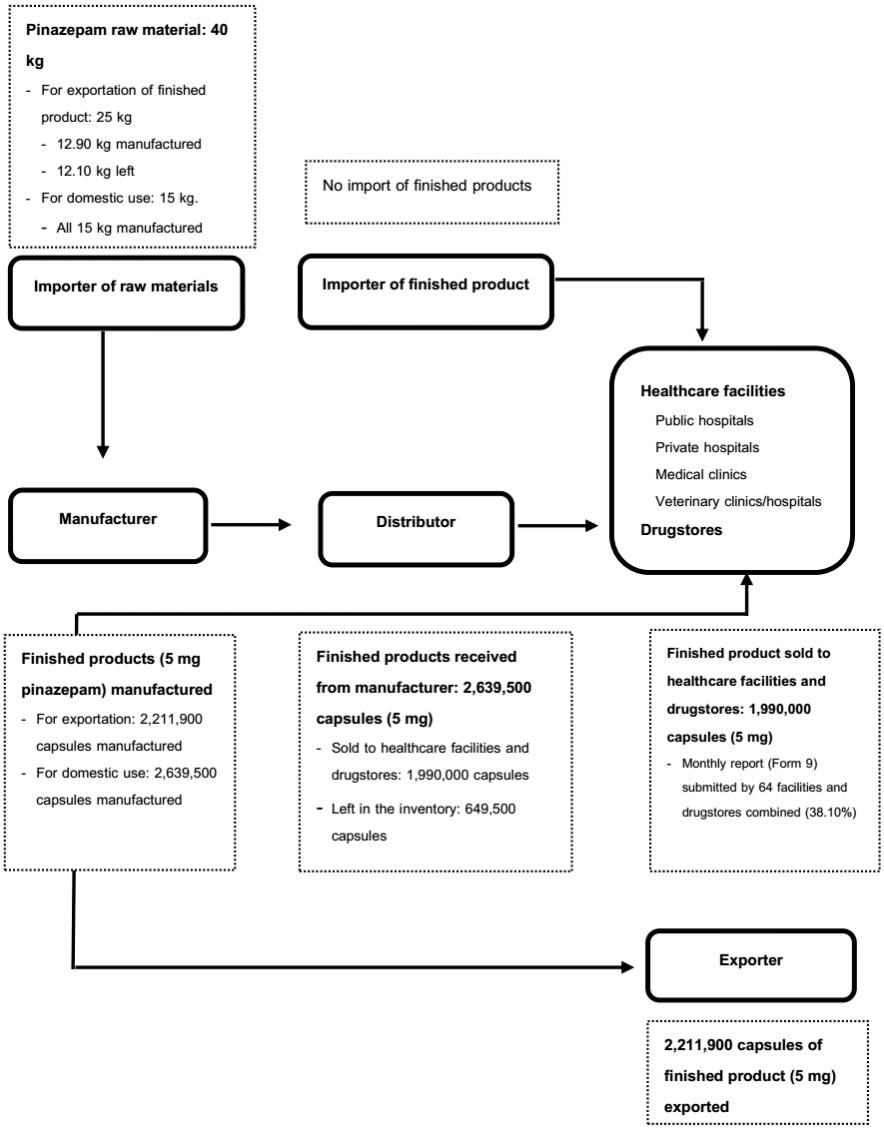

Figure 4 The verification of the volume of pinazepam raw material and finished product from January 2014 to July 2015.

Second, the data of the volume of pinazepam finished products healthcare facilities and drugstores received and sold/dispensed to the patients were incomplete. This was because healthcare facilities with the possession of not more than 5 grams of the substances or 10,000 capsules/tablets of the finished product were not required by law to apply for possession permission. Hence, it was impossible to enforce them to submit the monthly report (Form 9) to the FDA. Thus these facilities might submit the report voluntarily. It was therefore impossible to know the extent of the incomplete information and hence the leakage from healthcare facilities to the end users and/or other agencies.

Based on the monthly report (From 9) from the manufacturer and distributor, pinazepam finished products were sold to 168 healthcare facilities and drugstores combined. Of these 167 agencies, only 64 submitted their monthly report (Form 9) to the FDA while the rest (104 agents or 61.90%) did not. The distribution from healthcare facilities and drugstores to end users was thus difficult to verify. In addition, healthcare facilities were subject to completing the balance between purchase and dispensing/sale volume of psychotropic substance finished product (Form 8) and having the report ready for on-site inspection. Drugstores were also required to complete the reports of individual purchase activities of psychotropic substance finished product (Form 4) and dispensing activities of psychotropic substance finished product by prescription (Form 5) and have them readily available for

inspection at their venues. Since the FDA was not adequately staffed, the on-site inspection on these reports was almost impossible. In the near future, the availability and requirement of online reports to healthcare facilities and drugstores could help the inspection possible.

Based on the findings described above, reporting system of psychotropic substance in Thailand using pinazepam as the study drug was defective. It was difficult to verify the agreement of the amount or volume of pinazepam raw material and finished product at each relevant step of distribution. With a limited number of 7 officers at the FDA, specifically 5 individuals responsible for inspecting reports from importers, manufacturers and distributors and 2 for those from healthcare facilities and drugstores, it was impossible for them to inspect the distribution of all psychotropic substances at all relevant steps. The task of verifying the data at all steps of distribution was time-consuming and labor-intensive. The verification on pinazepam which was the drug with only one manufacturer and one distributor took as long as one month to complete. If hiring more staff members for the task was not feasible, we speculated that the mandatory online reporting system for healthcare facilities and drugstores could help these officers to effectively inspect the reports. We recommended an online system similar to CSOS (Controlled Substances Ordering System)[5] of the US to help verify data in all reports in a timely fashion for a more efficient vigilance system.

Based on the findings, specific recommendations are as follows. The FDA could improve the process of data verification through reporting system at all steps of the distribution of psychotropic substances. The three specific steps could be improved. First, the volume of the imported psychotropic substance raw materials the importers asked for permission at the Pre-marketing Control Unit should be checked with the volume reported at the Custom Department as well as the volume reported at the Post-marketing Control Unit. Second, the volume of manufactured finished products that were sold to the distributor should be checked with the volume the distributor received. Third, the volume of the products the manufacturer and distributor sold to healthcare facilities and drugstores should be checked with the volume the healthcare facilities and drugstores received.

We also recommend that the online E-Logistics system could be improved. The FDA could adapt the concept and logistic system from the Controlled Substances Ordering System (CSOS) of the US so that a more comprehensive electronic reporting system could be achieved. This upgrading could also help alleviate the problem of under-staffing.

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Editorial note
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