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THE IMPLEMENTATION AND MAINTENANCE OF PRINCIPLES FOR GOOD DISTRIBUTION PRACTICE: A SURVEY ON PHARMACEUTICAL DISTRIBUTION COMPANIES IN HO CHI MINH CITY, VIETNAM

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ABSTRACT

Objective: *Vietnam's Ministry of Health has issued a circular on good practice distribution (GDP) to ensure the quality of drug dispensation from manufacturers to consumers. However, the Department of Health in Ho Chi Minh City (HCMC) faces many challenges and difficulties in adhering to the mandate. Motivated by this problem, this study administered a survey to drug distribution companies in HCMC to determine the manner by which they implement and maintain GDP.*

Methods: *This cross-sectional descriptive study was conducted in June 2017 and involved 192 drug distribution companies located in the study site. The survey was intended to identify common violations that the companies commit in the process of applying and maintaining GDP requirements.*

Results: *Amongst the companies, 19 (10% of the sample) did not have pharmacists in charge of drug distribution or employed ones that do not have the required professional qualifications, 54 (28%) did not satisfy requirements on storage volume and warehouse capacity and 23 (12%) imposed unsatisfactory limits on warehouse temperature. Most of the surveyed companies (157) conformed to appropriate transportation conditions.*

Conclusion: *The surveyed companies underperformed with respect to GDP-related requirements regarding human resources, warehouse (storage) facilities and vehicular capacity, but they exhibited relatively satisfactory documentation and recording practices.*

Key words: *Good practice distribution, GDP, Ho Chi Minh City, Vietnam.*

INTRODUCTION

Amid regional and international economic integration, the pharmaceutical industry of Vietnam has become a foremost concern of the country, especially since its membership in the World Trade Organization in November 2006 [1]. This industry is accorded priority not only because it is an important business domain but also because it reflects the value that the ruling party and the state place on health care for Vietnamese citizens. On the basis of the functions, duties and powers of the pharmaceutical industry, Vietnam's Ministry of Health officially issued a circular on good distribution practice (GDP) to guarantee comprehensive and high-quality drug distribution, with the stipulations covering the production, testing, storage and wholesale and retail stages of the supply chain. GDP standards also apply to import–export transactions, transportation, forwarding businesses, drug storage and distribution by national health programs [5, 6]. GDP implementation is part of endeavours to maintain drug distribution quality through full control of all activities related to drug delivery [2]. It comprises basic principles and general guidelines for favourable drug delivery practices and articulates drug delivery requirements, thereby ensuring the timely and qualitatively sound conveyance of medications to consumers [3, 4].

The implementation of GDP in pharmaceutical distribution companies/institutions in Ho Chi Minh City (HCMC) is under the management of the HCMC Department of Health, where three divisions are tasked with responsibilities directly related to pharmacological governance: the Drug Administration Department, the Inspection Department and the Health Services Management Department. The Drug Administration Department manages the professional activities of the pharmacy departments of hospitals, faculties of preventive medicine, pharmaceutical companies, pharmacies and certain production facilities. The management of GDP implementation in HCMC is confronted with numerous challenges, amongst which the shortage of personnel is particularly worrisome. An inadequate workforce is devoted to GDP implementation under dizzying increases in the number of pharmaceutical enterprises operating in HCMC (1,051 pharmaceutical distribution companies/institutions as of October 20, 2015), the volume of drugs circulating in the city, the number of GDP model formats used and the scales of companies. For example, only more than 20 university pharmacists are currently working at the Department of Health in HCMC. The situation discussed above highlights the need to survey and evaluate whether drug distribution companies/institutions satisfy GDP standards on personnel issues, drug storage, drug transport and documentation systems; an equally urgent requirement is to propose solutions for improving the GDP performance of these firms [7, 8]. Accordingly, this study was carried out to investigate the implementation of GDP requirements by drug distribution companies/institutions in HCMC, Vietnam.

MATERIAL AND METHODS

Study design

This cross-sectional study was intended to assess GDP application in drug distribution companies/institutions that are established and operating in HCMC.

Study site

This research was conducted in June 2017 at HCMC ($10^{o}46'N$, $106^{o}42'E$), which is the capital of Vietnam and the largest city in the south-eastern region of the country [9]. Located about 1,760 kilometres south of Hanoi, HCMC spans 2,097 square kilometres and had a population of over 14 million in 2017 [10, 11]. This city is the economic centre of Vietnam, accounting for 21.3% of the country's gross domestic product and 29.4% of the total national budget in 2012 [11]. HCMC boasts of a well-developed healthcare system that comprises a chain of about 100 government-owned hospitals or healthcare centres and dozens of privately-owned hospital and clinics.

Study subjects

A list of 463 pharmaceutical companies in HCMC was obtained from the authority office, after which the firms were numbered from 1 to 463. Participant companies were selected using cluster sampling [12], in which one company was randomly chosen, then after three counts, another firm was selected. This process continued until the counting returned to the first company, leaving us with a final sample of 192 firms.

Study instrument

This research evaluated the following GDP issues: organisation and management; personnel; facilities, warehouses and preservation; means of transport and equipment; delivery and shipment; transportation and drug storage; and documentation [6]. A checklist was designed after a discussion amongst a panel of experts from different fields, including a pharmacist, a businessman, a lawyer and a governmental manager. The checklist was based on the latest government documents on GDP. Ten volunteers were trained to manage the checklist prior to visits to the sample companies/institutions. These volunteers are employees of the authority office and are also inspection specialists.

Data analysis

Collected data were entered into Microsoft Excel version 2010, and descriptive statistics were used to render the results in frequency and percentage. No further statistical analysis was conducted because of time limitations.

RESULTS

As previously stated, this study assessed the GDP performance of 192 drug distribution companies in accordance with the seven proposed GDP-related issues.

Organisation and management

All the companies had full legal status at the time of the survey.

Personnel

The results on personnel indicators are presented in **Table 1**. Amongst the surveyed institutions, 173 (90% of the total) employed university pharmacists, 15 (8%) failed and 4 (2%) did not employ such personnel. Specifically, in a given campus, the lowest number of pharmacists present was 0, whereas the highest was 10, indicating an average of 2.4 university pharmacists. With respect to high school pharmacists (storekeepers), all the institutions kept up with demand, having an average of 4.6 such employees per facility. The lowest number of high school pharmacists in each institution was 1, whereas the highest was 23. More than 90% of the institutions/companies fully implemented a process for handling employee safety or GDP training for highly qualified employees, but employees in 19 (20%) of the establishments were not directed to wear appropriate protective clothing.

Table 1: Results on adherence to personnel requirements (n, %)

Requirement	Yes		No	Standard
	Pass	Fail		
Pharmacist with a bachelor's degree (BP)	192 (100%)	-	-	-
Intermediate pharmacist (storekeeper)	173 (90%)	15 (8%)	4 (2%)	2.4 BP (Min = 0, Max = 10)
Intermediate pharmacist (delivery, biological products ...)	192 (100%)	-	-	4.6 IP (Min = 1, Max = 23)
Is there a process for handling cases that affect employee safety?	184 (96%)	8 (4%)	-	-
Are employees trained in GDP?	180 (94%)	12 (6%)	-	-
Do employees have workwear?	154 (80%)	19 (20%)	-	-

Facilities, warehouses and preservation

As shown in **Table 2**, the storage facilities of the drug distribution businesses consisted of areas such as storage, shipping and receiving and sampling sections. The number of companies/institutions that satisfied the requirements for each section differed. For instance, more than a quarter of the surveyed establishments (28%) did not meet requirements on the size of storage areas and the volume of drugs that they should be able to handle.

Table 2: Results on adherence to storage facility requirements (n, %)

Requirement	Yes		No	Standard
	Pass	Fail		
The warehouse has its own areas, arranged appropriately for the following purposes:				
Storage	184 (96%)	8 (4%)	-	-
Shipping/receiving	173 (90%)	19 (10%)	-	-
Sampling	-	-	192 (100%)	-
Reservation: Disqualified, expired, recalled drugs	192 (100%)	-	-	-
The area and capacity for drug storage area are sufficient and reasonable.	138 (72%)	54 (28%)	-	-
Are the temperature and humidity of the storage area appropriate?	169 (88%)	23 (12%)	-	Average temperature: 27°C (23°C–31°C)
Are devices used to monitor storage conditions periodically calibrated?	88 (46%)	104 (54%)	-	Average adjustment time: once every 22 (12–35) months

The results on adherence to temperature and humidity requirements is more positive, with only 23 companies/institutions (12%) failing in this regard. The equipment used to monitor storage conditions were not understood by many businesses, with only 88 of them having periodically checked such devices. The sizes of storage sections, the volumes of drugs that they are capable of storing and their coefficients are presented in **Table 3**.

Table 3: Average areas (sizes) and volumes stored

Item	Value
Average actual area	81m^2 (32–425 m^2)
Average queue area	50m^2 (15–220 m^2)
Average actual volume	285m^3 (102–2175 m^3)
Average volume of loading	127m^3 (22–880 m^3)
Average area utilisation factor	0.63 (0.52-0.85)
Average volume usage coefficient	0.45 (0.21-0.78)

Means of transport and equipment

Of the companies/institutions surveyed, 157 satisfied transportation standards, with these establishments having averages of 1.4 and 1.7 cars and motorcycles, respectively. However, the accepted process of cleaning vehicles and the required storage conditions during transportation were haphazardly followed, with only 58% and 52% of the establishments satisfying these standards, respectively. More details are shown in **Table 4**.

Table 4: Results on conformity with requirements for vehicles and equipment (n, %)

Requirement	Yes		No	Standard
	Pass	Fail		
Does the transporter protect drugs and packaging from outside agents? What type of transport is used?	157 (82%)	35 (18%)	-	Average number of cars: 1.4 units Average number of motorcycles: 1.7 units
Are transport cleaning procedures conducted and recorded?	112 (58%)	19 (10%)	61 (32%)	-
Are storage conditions maintained within permissible limits and monitored continuously during transport? IS tracking recorded and kept on file?	100 (52%)	84 (44%)	8 (4%)	-

Delivery and shipment, transportation and drug storage

Table 5 shows data on delivery, shipping and drug storage requirements during transportation. All the surveyed companies performed well with respect to these principles.

Table 5: Results on adherence to delivery, shipping and drug storage requirements during transportation (n, %)

Requirement	Yes		No
	Pass	Fail	
Is there a way to isolate drugs that need to be stored during transport?	192 (100%)	-	-
Is it possible to build delivery and route schedules? Are these schedules feasible?	192 (100%)	-	-
Is the principle of loading/unloading followed?	192 (100%)	-	-
Is there any measure for avoiding collapse when loading and unloading?	192 (100%)	-	-

Documentation

Standard operating procedures and job descriptions were satisfactorily implemented by all the surveyed companies/institutions (**Table 6**), but control over the execution of standard processes were inadequately put into practice, with only 54% having ensured conformity to these principles. The evaluation also revealed little interest in achieving uniformity in warehouse storage areas, as evidenced by the fact that only 69 of the establishments met the requirements.

Table 6: Results on conformity with documentation requirements (n, %)

Requirement	Yes		No	Standard
	Pass	Fail		
Are there standard operating procedures for writing operations?	192 (100%)	-	-	Average SOP: 30 (Min = 26, Max = 45)
Are these procedures implemented?	104 (54%)	88 (46%)	-	
Is there a job description for each individual?	192 (100%)	-	-	
Is there a profile for assessing the uniformity of storage areas?	69 (36%)	123 (64%)	-	Average: once every 27 months

A total of 92 (48%) companies recorded all activities related to operations, and 119 (62%) establishments kept records of receiving goods (**Table 7**). Of the surveyed companies, 90% (172 establishments) took and stored inventories, and up to 82% satisfactorily monitored the storage conditions in warehouses. However, inadequate focus was directed towards the monitoring of sanitation in the warehouses, with only 92 facilities exhibiting satisfactory practices and 54 having failed to implement corresponding measures.

Self-inspection and periodic testing are essential requirements for drug distribution companies. In this respect, most of the businesses surveyed have conducted periodic self-evaluations (130 enterprises, 68%), and a number of other establishments (58 business) carried out tests, albeit the manner by which these were performed were unsatisfactory. Of the 192 drug distribution enterprises surveyed, only 31 (16% of the total) were qualified to carry out internal self-inspection, and over 60% did not have such testing/evaluation in place.

Table 7: Results on adherence to recording requirements (n, %)

Requirement	Yes		No
	Pass	Fail	
Are records related to all recorded activities at the time of each operation?	92 (48%)	100 (52%)	-
Do you create and save receipts?	119 (62%)	19 (10%)	54 (28%)
Are inventory records stored and saved?	172 (90%)	8 (4%)	12 (6%)
Is the monitoring of storage conditions in a warehouse fully recorded?	157 (82%)	31 (16%)	4 (2%)
Is monitoring of sanitation fully recorded?	92 (48%)	46 (24%)	54 (28%)
Is there a periodic self-test? How often is this conducted?	130 (68%)	58 (30%)	4 (2%)
Are sudden self-examinations conducted?	31 (16%)	38 (20%)	123 (64%)

DISCUSSION

In many of the examined drug distribution companies, no university pharmacists were in charge of managing distribution, their employees have not received GDP training and no suitable labour protection measures were enacted. This study recommends the employment of at least one university pharmacist in charge of special distribution activities, the formulation of a plan for GDP training at the beginning of each year and the implementation of regulations regarding appropriate protective clothing for each job. In the matter of

facilities, warehouses and preservation, some sections in the warehouses were inappropriately designed and arranged; these sections are the storage, delivery/receipt and sampling areas. Additionally, the companies did not create suitable cleanliness, dryness, moisture and temperature conditions in their storage areas. Storage capacity also fell short of GDP standards, and the periodic calibration of equipment used to monitor storage conditions was neglected. These problems can be overcome by appropriately designing and arranging storage, receiving/exporting and sampling areas. These areas should likewise be checked regularly to ensure conformity with temperature and humidity requirements. Monitoring equipment should be calibrated, maintained and checked periodically to guarantee accuracy. Other measures include equipping warehouses with additional refrigerators, increasing the standards for the preservation of vaccines and medical biologicals, ensuring adherence to FIFO (first in, first out) and FEFO (first expired, first out) principles, checking all lots and dividing and arranging medications in rows of separate date lots, page added, date lottery device.

The companies had inadequate and unsatisfactory transportation and equipment, and they disregarded suitable processes for cleaning vehicles and recording such activity. Special storage conditions (for vaccines, medical biological products, etc.) were intermittently monitored, and temperature consistency in the storage sections of transportations was neglected. These issues can be rectified by ensuring that medicinal products are delivered using adequate transport facilities (at least one vehicle). Vehicles should be properly cleaned, and the instances at which cleaning is performed should be documented. More specialised motorbikes should be added to the fleet of delivery vehicles. To maintain special storage conditions, transportation personnel need to keep track of the current conditions of vaccines and medical biologicals. Before placing goods in shipping containers, a necessary task is to guarantee uniformity in temperatures inside storage containers and vehicles.

Finally, as regards documentation, procedures related to drug trading were violated, and inadequate records were maintained with respect to operations, the monitoring of storage conditions and sanitation. Self-inspections were conducted periodically, but no unscheduled examinations were performed. Suggestions for resolving these problems are companies should clearly and fully record information at the time each activity is performed (which employees performed a given task, what has been accomplished, how these were accomplished, etc.). Another essential measure is to ensure compliance with FIFO–FEFO principles during allocation to facilitate the acquisition of accurate information on each batch of products. Pharmaceutical trading companies should conduct periodic self-inspection on all activities to ensure business quality, and unscheduled inspections should be conducted in parallel to promptly detect errors in business and management.

CONCLUSION

In summary, the analysis conducted in this work indicated the satisfactory implementation of GDP by pharmaceutical companies in HCMC. Nevertheless, certain limitations still require resolution. The recommendations put forward in this work should be considered by the surveyed companies to assess the feasibility and prospects of the proposed solutions to the current GDP-related deficiencies in the city. After implementing the proposed solutions, GDP management processes should be re-evaluated to identify the best measures for enriching the application of GDP in drug distribution businesses.

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CONFLICTS OF INTERESTS

The authors have no conflicts of interests to declare.

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