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An Update of Herbal Medicines Situation Analysis in Ho Chi Minh City, Viet Nam

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ABSTRACT

In Ho Chi Minh city, herbal medicines have widespread expansion in both quality and quantity but the quality of those medicines still remain unequal. This prospective research was designed to analyze production status on traditional medicines in Ho Chi Minh City and was aimed to suggest some solutions for achieving GMP in pharmaceutical drugs. Information about production traditional medicines in the period of 2004-2011 were gathered. In addition, the study, using cross-sectional description method, was organized to interview representatives of 13 manufacturers in pharmaceutical drugs in accordance with the principles of manufacturing medicines stipulated by Circular/16/2011/Circular-MOH in 2011. The number of facilities manufacturing increase constantly from 74 facilities in 2004 to 108 those in 2011. Manufacturers were registered as four business categories: joint stock companies, limited liability companies, joint ventures, and household business (the highest rate - 80.6% in 2010). This is a consequence in that the traditional dosage form constitutes 70.8% of 665 circulating registrations number. The quality of traditional medicines still remains low over the year account for 68.6%, and 33.3% of health facilities have adapted the GMP standard in 2010. Current situation of manufacturing traditional medicines in 13 facilities pursuant to the Circular 16/2011/Circular-MOH. Together these results provide important insights into the status of manufactured traditional medicines in Ho Chi Minh City. The manufacturing of traditional in Ho Chi Minh City is growing. The quality of medicines has gradually increased since facilities had applied the basic principles of circular 16/2011/Circular-MOH and GMP.

INTRODUCTION

Nowadays, trends in the world in general and Vietnam, in particular, to return to nature so the need to use traditional medicines and pharmaceutical drugs is increasing. Having developed traditional medicine for a long time, Vietnam own many unique and effective treatment methods. In light of heredity and developing this legacy, accompany with having direct and focus strategies to progress properly, the government have decidedly enacted approval regulations, decision to ensure the quality of traditional medicines. However in the presence of Decision of 15/2008/Decision-MOH [1] and GMP standard for organizations producing traditional medicines published on early September 2010, there was less than one-third (32.4%) of the facilities can reach the regulations of GMP and the decision of 15/2008/Decision-MOH in producing medicines. This result may be explained by the fact that there are difficulties in sources of capital, building, equipment status and human resources. Another possible explanation for this is that many regulations in decision of 15/2008/Decision-MOH don't prove quite rational, thus, requiring a reasonable amount of amendment. Otherwise, manufacturers must improve production process and quality of these traditional medicines. This paper provides an overview of producing status on traditional medicines in Ho Chi Minh City. The specific objective of this study was to ascertain producing a status of 13 facilities in Ho Chi Minh City is pursuant to the Circular 16/2011/Circular-MOH[2], and to suggest solutions for achievement GMP in pharmaceutical drugs.

MATERIALS AND METHODS

Ho Chi Minh City, which is located in Southern Vietnam, is the largest city in Vietnam with 24 districts, capturing an area of 30000 square kilometres and accommodating a population of more than seven million inhabitants (2014). Having advantageous position not only in Vietnam but also in Southeast Asia with important ports, Ho Chi Minh City possess great opportunity to develop in economic, culture, science technology and so on [3]. This study was conducted informally in 13 premises of the manufacture of traditional medicines in Ho Chi Minh City.

Table 1. Name of the manufacturers of traditional medicines in Ho Chi Minh City

1. Sai Gon Pharmaceutical Limited liability company (Sagopha)	8. AnhDao Manufacturing establishments of Traditional Medicine
2. Van Xuan Pharmaceutical Limited liability company	9. Dai Duc Manufacturing establishments of Traditional Medicine
3. Chanh Dai Manufacturing establishments of Traditional Medicine	10. Dong Hue Manufacturing establishments of Ethnic Medicine
4. Son Ha Manufacturing establishments of Medicated Oil	11. Hai Thuong Manufacturing establishments of Traditional Medicine
5. Thai Duong Manufacturing establishments of Traditional Medicine	12. A Tien Manufacturing establishments of Traditional Medicine
6. NhanPhong Duong Manufacturing establishments of Traditional Medicine	13. Kim Nguyen Duong Manufacturing establishments of Traditional Medicine
7. Phuoc A Manufacturing establishments of Traditional Medicine	

Data for this study were retrospectively collected from 2004-2011 included the number of manufacturing facilities, facilities granted with new certificates of eligibility for drug trading, traditional medical clinics and number of traditional medicines of unsatisfactory. Otherwise, cross-sectional description was carried out on the implementation of GMP and the Decision of 15/2008/Decision-MOH; businesss type; the registration scope; valid registration numbers up to September 2010. Direct interviews and distribution of questionnaires to representatives of facilities manufacturing in Ho Chi Minh City were completed in accordance with the principles of producing medicines stipulated by circular 16/2011/Circular-MOH from 04.2011-06.2011. Data management and analysis were performed using Microsoft Excel 2010.

RESULTS AND DISCUSSION

When statistics on the number of facilities and those with newly-issued certificates of eligibility for drug trading over the years, the number of manufacturers of tradition went up from 72 facilities in 2004 to 102 of those in 2007, before going down to 99 facilities in 2008, and finally reaching 108 producers in 2010, 2011. A possible explanation for this might be that the government had forced

many facilities to close because they did not satisfy the regulations in decision 15/2008/Decision of MOH which was approved in 2008. From 2009 to 2011, the amount of facilities granted with new certificates had risen again, especially 22 manufacturers had new certificates in 2010.

Table 2. Number of facilities and facilities granted with new certificates of eligibility for drug trading over the years

Number	2004	2005	2006	2007	2008	2009	2010	6/2011
Facilities	74	94	99	102	99	104	108	108
Facilities granted with new certificates of eligibility for drug trading		15	9	13	4	7	22	

Table 3. Statistics by type of business category

Ordinal Number	Business category	Quantity	Percentage
1	Joint stock company	9	8.3
2	Limited liability company	11	10.2
3	Joint venture company	1	0.9
4	Household business	87	80.6
	Total	108	100

Statistics on herbal medicine's production facilities from existing data by type of business category as of September 2010, Ho Chi Minh City had 108 facilities, registered as four business categories: joint stock companies, limited liability companies, joint ventures, household business of which household business account for the highest rate (n=87, 80.6%) in the other hand joint venture company had the lowest proportion at only 0.9% (see Table 3).

Traditional medicines also are made by many traditional medicine clinics so that those medicines have a variety of forms and number.

Table 4. Statistics of the number of traditional medicine clinics over the years

Number	2005	2006	2007	2008	2009	6/2010
Traditional medicine clinics	962	997	1,049	1,035	1,048	1,061

It can be seen from the data in Table 4 that the number of traditional medicine clinics had increased significantly since 2005, then there were 1061 those clinics in June 2010.

About a number of shortcomings about the quality of pharmaceuticals materials and herbal medicines,the quality of pharmaceutical materials are directly linked to the quality of herbal medicines. In both decision 15/2008/Decision-MOH and circular 16/2011/Circular-MOH, the quality of herbs is the first regulations in producing pharmaceutical drugs and traditional medicine.

Table 5. Statistics on quality of pharmaceutical materials in 2007, 2009, 2010

Number	Satisfactory		Unsatisfactory		Total	
	Quantity	Percentage	Quantity	Percentage	Quantity	Percentage
2007	23	44.2	29	55.8	52	100
2009	63	75.0	21	25.0	84	100
2010	16	31.4	35	68.6	51	100

As can be seen from Table 5, the rate of unsatisfactory pharmaceutical materials was 55.8% (2007) and 68.6% (2010). Pharmaceutical materials, which those active ingredients were extracted, weren't easy to recognize without testing. To assess and ensure the quality of plant materials, that is needed more effective plans. According to Laboratory Centre of Medicines - Cosmetics-Food Ho Chi Minh City, the rate of unsatisfactory pharmaceutical drugs was 22.9 percent in 2007. In 2008, 2011, that rate was 7.1 and 12.6, respectively. A possible explanation for these results may be that the quality of pharmaceutical drugs had been controlled effectively since decision 15/2008/Decision-MOH was received approval. Statistics on the number of facilities with/without certificate of eligibility for drug trading up to September 2010, the proportion of facilities without certificate was 27.8%, mainly household business. Otherwise, 100% of the company was granted certificate. These results are likely to be related to difficulty in having new certificate related with new standards. The quality of medicines must be assessed carefully to ensure safety in treatment in spite the fact that the amount of pharmaceutical drugs dramatically decreased.

The implementation of GMP and the Decision of 15/2008/Decision-MOH

Table 6. Statistics on implementation of GMP and the Decision of 15/2008/Decision-MOH

Business category	Granted certificate of eligibility for drug trading			Without certificate of eligibility for drug trading(Percentage)	Total (Percentage)
	Achieve standards (Percentage)	Having plan, under construction (Percentage)	Not achieve standard (Percentage)		
Company	7 (33.3%)	2(9.5%)	12 (57.2%)	0 (0%)	21 (100%)
Household business	28 (32.2%)	0 (0%)	29 (33.3%)	30 (34.5%)	87 (100%)
Total facilities	35 (32.4%)	2 (1.9%)	41 (38.0%)	30 (27.7%)	108 (100%)

Up to September 2010, there were 32.4% of total facilities which had met standards set by GMP. 33.3% of the company had met standards of GMP, 32.2% of household business had those too. Beside that some manufacturers are going to upgrade their facilities to grant standards set by GMP, many manufacturers did not want to make their facilities better. This result can be explained that their drug, which made by the old process, still has good treatment the patient.

For statistics on the registration scope of traditional medicines up to September 2010, the manufacturers must register particular scope on their producing to make specific form of medicine. Nowadays, the facilities not only registered on traditional forms but also modern forms [4].

Table 7. Registration scope on modern forms

Ordinal Number	Registration scope (modern forms)	Enterprises	Household Business	Total Quantity	Percentage
1	Tablets	10	4	14	33.33
2	Capsules	9	5	14	33.33
3	Others (patches, eye drops, nose drops, under skin implanted, inhaler...)	11	3	14	33.33
	Total	30	12	42	100

Table 8. Registration scope on traditional forms

Ordinal Number	Registration scope (traditional forms)	Enterprises	Household Business	Total Quantity	Percentage
1	Solid pills	7	23	30	22.2
2	Softpills	3	13	16	11.9
3	Medical solutions	9	21	30	22.2
4	Medical solutions for external use	10	22	32	23.7
5	Medical powder	3	14	17	12.6
6	Extract	3	1	4	3.0
7	Others (extract patches, teas…)	5	1	6	4.4
	Total	40	95	135	100

Table 9. Statistics on manufacturer's registration scope

Forms	Enterprises	Household Business	Total	
			Quantity	Percentage
Traditional dosage	40	95	135	76.3
Modern dosage	30	12	42	23.7
Total	70	107	177	100

In summary, Table 9 shows that the manufacturers registered on traditional forms more than those on modern forms with 76.3% and 23.7%, respectively. The facilities registered traditional dosage forms mainly in medical solution, solid pills and medical solution for external use with 29.9%; 18%; 17.4%, respectively. The manufacturer's registration scope in modern dosage forms were mainly tablets (33.33%) and capsules (33.33%) because of its advantages in precise dosage, easy to store, carry and use. These forms were produced mainly by enterprises due to high technology, modern machines. Although investment costs for research in producing pharmaceutical drugs in modern forms were expensive, there had much potential for both quality of medicine and economic benefit.

Table 10. Statistics on traditional drug circulating registration numbers in Ho Chi Minh City

Forms	Enterprise	Household business	Total	
			Quantity	Percentage
Traditional dosage	165	306	471	70.8
Modern dosage	192	2	194	29.2
Total	357	308	665	100

For statistics on the registration numbers of herbal medicine were produced by the manufacturer which had a valid certificate of eligibility for drug trading up to September 2010, herbal medicine's market had many different varieties of dosage forms. Modern dosage forms were developed recently alongside traditional dosage forms. Household business mainly produced traditional dosage forms with 70.8% and 29.2% of modern dosage forms. The rates of traditional and modern dosage forms which were produced by enterprises were nearly equal. From the

graph above we can see that household business primarily provided traditional dosage form of herbal medicine while company produced both 2 dosage forms but modern forms were focused.

Table 11. Statistic on the facilities which had valid certificate, registration scope, and registration number

Facilities	Business category		Registration scope		Registration number	
	Quantity	Percentage	Quantity	Percentage	Quantity	Percentage
Enterprise	21	26.9	70	39.5	357	53.7
Household business	57	73.1	107	60.5	308	46.3
Total	78	100	177	100	665	100

Despite the fact that the enterprise accounts for only 26.9% of total manufacturers in Ho Chi Minh City, they also played an important role in producing herbal medicines through 39.5% of registration scope and 53.7% of registration number. Household business has their own essential in developing traditional medicines, pharmaceutical drugs with 46.3% of registration number. According to circular 16/2011/Circular-MOH about situation analysis of herbal medicine derived from data on the Ho Chi Minh City, pharmaceutical materials must have information on medical herbs, harvesting methods, processing, and preservation. However, national pharmaceutical materials can provide just 20% of producing's need, the shortage of those materials was imported from China. Manufacturers buy pharmaceutical materials from the provider mainly depend on reputation and business relationship. 38.5% of total facilities had reported that their concern about the business condition of supplier and only 7.7% of total company had contract with the domestic supplier for plant pharmaceutical materials and quality of those materials. Besides the quality of pharmaceutical materials, human resources are also the key issues for long-term developing of any types of business. In fact, enterprises had more employees than household business. Moreover, company also had more high-level workers than household business. Intermediate pharmacist and assistant pharmacist accounted for the highest rate with 35.3% and 24.3%, respectively. Family was the origin of household business; except householder had the highest degree like doctor, physician... both number and degree of workers were limited, particularly the proportion of general worker were 59%. The facilities building and equipment was upgrading, many facilities currently

have right investments so that the rate of facilities which met this regulation were higher than those did not meet this standard). Most houses used to produce drugs (first floor, second floor or terrace).

The result revealed that there were 8 out of 13 facilities that met the standards for label. In 13 facilities interviewed, there still had 2 facilities that did not establish their own SOP. Of the 13 participants who responded to this question, 11 reported meeting the standards for hygiene. Manufacturers were going to improve hygienic conditions to conform to Government's regulations. In summary, control in producing process, labelling, hygiene… were quite good especially those facilities that met standards in producing pharmaceutical drugs, traditional medicines. The number of manufacturers, which granted these standards, was 11 out of 13. There were 11/13 facilities had met the criteria in complaint and product recall. These standards weren't difficult to achieve if they try to learn experiences from other facilities that had met standards and guidance from Minister of Health. Through surveys, the proportion of facility met these criteria were 11/13. Decision 15/2008/Decision-MOH and circular 16/2011/Circular-MOH contributed to producing pharmaceutical drugs better. Follow these regulations, the manufacturers had to have their own specific plans for self-inspection for example: inspectors, self-inspection's report to improve, and so on.

For the management of the state in control of pharmaceuticals, traditional medicines, the statistics in 2007, 2009, 2010, the unsatisfactory pharmaceutical rate were between 25 and 68.6% of the tested samples. Especially, that rate reached peak 68.6% in 2010. Meanwhile, status of the laboratory in pharmaceutical materials was not good enough lead to using unsatisfactory herbs. Nowadays, many manufacturers could not plant pharmaceutical materials while producing medicines. Above that, domestic herbs had not enough to supply producing activity in Vietnam and China's pharmaceutical materials were not ensure good quality. Agency of Laboratory had a response to test periodically to control quality of herbs. Otherwise, the management of the state in control pharmaceutical's quality and pharmaceutical material supplier and have not available as yet. On December 2007, Department of health in Ho Chi Minh City established Room Pharmaceutical Drugs Administration but, the activity of this room were not effective. There is currently an overlapping in the management of medicine in Ho Chi Minh City.

CONCLUSION

The manufacturing of traditional medicines in Ho Chi Minh City is growing. But the quality of both pharmaceutical materials and herbal medicines weren't good enough. To solve those problems, the government should plan many domestic large cultivation areas for growing pharmaceutical materials in accordance with principles of GACP-WHO as well as ensuring these products could be used properly. Up to 9/2010, Ho Chi Minh City had 108 manufacturers in traditional medicines. They registered as four business categories: joint stock companies, limited liability companies, joint ventures, and household business. There were 78/108 facilities had certificates of eligibility for the drug (include 21 company and 57 household business). Beside that 30/108 facilities, which were household business, had outdated certificates of eligibility for drug. Nowadays, modern dosage forms were also registered by the manufacturers alongside traditional dosage form. The Ministry of Health has granted 665 circulating registration numbers include traditional dosage form that accounts for 70.8% (mainly medical solution, solid pills) and modern dosage form for 29.2% (mainly tablets, capsules). In current growth status, the government and Minister of Health must improve both their management and simulation development in traditional medicines scope.

The standards in circular 16/2011/Circular-MOH currently are more suitable than decision 15/2008/Decision-MOH. The facilities have already had appropriate investments in accordance with circular 16/2011/Circular-MOH. Quality herbs had been improved before going into producing process. Human resources are still the cornerstone of manufacturer. The results obtained from the survey reveal that company was better at employee in both number and degree than household business. They are going to upgrade building and equipment present in accordance with new standards in circular 16/2011/Circular-MOH. Others standards of circular 16/2011/Circular-MOH were almost completed include hygiene and hygienic conditions, Files, Documents, Producing and Control, Complaint and product recall for facility and Self-inspection. With the manufacturers, improvement in their facilities are not only for being approval but also to give the best product for consumers. On the other hand, before approval new regulations, Minister of Health should consider their feasibility and suitability with reality.

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