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Investigation of the current state of drug use and opportunities for entry into the pharmaceutical industry in Vietnam

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1. Background

Since 2013, the Health Care Science Institute (IKEN) has been hosting an annual gathering of experts from industry, government, and academia to discuss collaborative approaches to improving public health and welfare. In 2015, it began conducting research on the subject of “Issues related to access to medicines and entry in the industry of emerging and developing nations.” It is believed that the global development of the Japanese healthcare industry cannot continue unless there is a shift of focus from developed nations, such as the European nations and the United States of America, to developing nations, such as the BRICS nations. However, there are various major challenges facing this prospect and multiple arguments have been proposed to overcome them. IKEN’s industry, government, and academia symposia invite lecturers and panelists who are familiar with the circumstances surrounding the stakeholders of the Association of Southeast Asian Nations (ASEAN) to receive inputs from various perspectives and conduct field investigations. Last year, IKEN conducted an overseas investigation of Indonesia to improve its understanding of the nation’s health policies and the strategies employed by the local industry. It revealed various issues regarding drug quality and appropriate use as well as manufacturing, export, and distribution.

The Socialist Republic of Vietnam was selected as the target nation for this year’s study. Vietnam is one of the several Asian nations that have experienced rapid economic growth in recent years. Along with income growth, the demand for pharmaceutical products is projected to rise in the country. However, Japanese entry into the Vietnamese pharmaceutical industry has caused the neighboring countries to lag due to various reasons such as a lack of awareness. Hence, building a foundation for basic information about Vietnam to support the future entry of Japanese businesses is an urgent task.

2. Purpose

The objectives of this fiscal year’s survey were to investigate (1) the current status of appropriate use of pharmaceuticals and the adverse event/drug quality monitoring framework in Vietnam and (2) the need for capacity building (including human resource development) in fields related to pharmaceuticals and healthcare, to shed light on the opportunities and challenges facing pharmaceutical companies that are considering entering the Vietnamese market in the future.

3. Methodology

Preliminary hearings with stakeholders were held prior to the field investigation. In addition, data concerning basic information about Vietnam (e.g., population, ethnic composition, religions) and its healthcare scenario were collected through a review of the extant literature. The field investigation was conducted for one week from March 20-24, 2017.

The field investigation mainly involved visiting relevant departments of the Vietnam’s Ministry of Health (Science, Technology, and Training, which conducts business related to the education of medical personnel; Medical Services Administration, which is responsible for all medical services; Drug Administration, which is related to product registration) as well as meeting the medical staff of the former Japanese Ministry of Health and Welfare dispatched to Vietnam by the Japan International Cooperation Agency (JICA) and Dr. Mitsuhiro Ushio, who is currently serving as Advisor to the Minister of Health in Vietnam. We also visited the World Health Organization’s (WHO) Vietnam office, Bach Mai Hospital, and several regional pharmacies. Finally, we gathered information from Japanese pharmaceutical companies that are currently operating in Vietnam (Table 1).

The content of this report, which is not reflected by the “References” section, is based on the data and findings obtained from field interviews.

Table 1

Preliminary Hearings	Field Investigation
MOFA	Ministry of Health, Viet Nam
MHLW	WHO Vietnam Office
JICA	Bach Mai Hospital
JPMA	Pharmacies in Hanoi
	Japanese businesses with local presence

4. Results

1) Current scenario in Vietnam

(1) Population dynamics (Ministry of Foreign Affairs of Japan, 2017; Ministry of Economy, Trade and Industry of Japan, 2016; Ministry of Health Vietnam, 2014)

Figure 1 displays the demographic trends in Vietnam. The population of Vietnam is approximately 95 million (2017), of which 34.7% is concentrated in urban areas. The average life expectancy is 76 years, but there are signs of decline in the birth rate and aging of the population (the birth rate is below 1.96). The rate of economic growth was 6.1% in 2016.

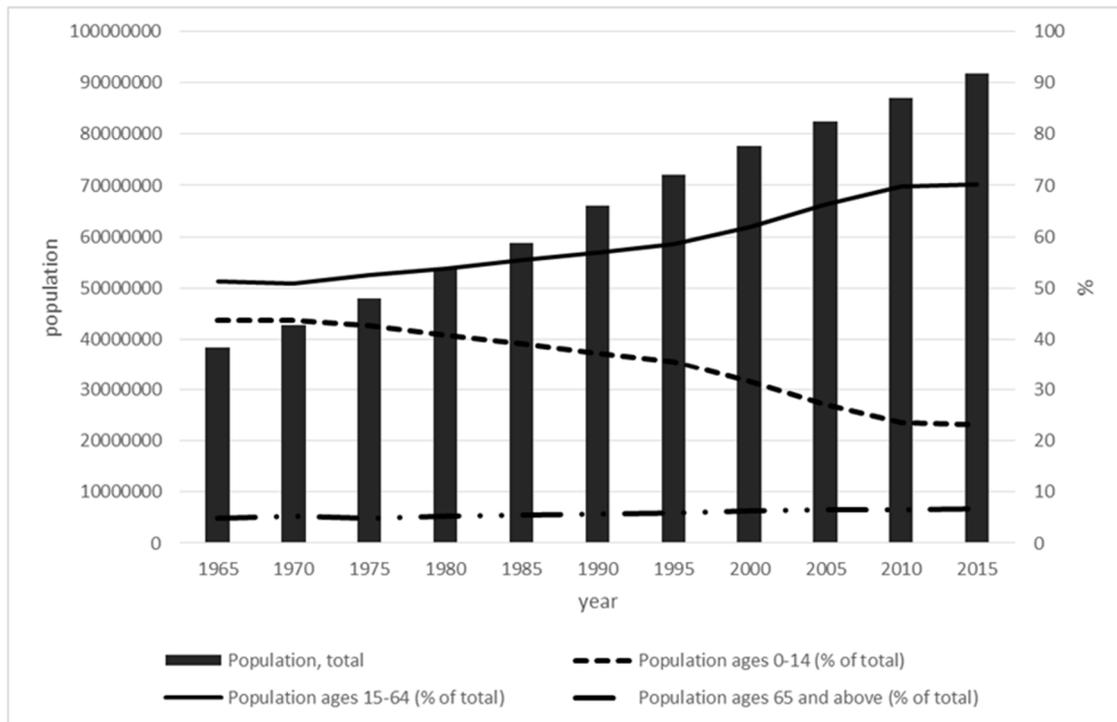


Fig. 1. Shifts in demography of Vietnam (Ministry of Health Vietnam, 2014)

(2) Disease structure

In Vietnam, noninfectious diseases such as chronic illnesses continue to become more prevalent (Fig. 2). As regards psychiatric disorders, such as depression, treatment is limited to psychiatric hospitalization despite an increase in the number of psychiatric patients. Thus, adequate care has not been provided to patients who require treatment. As such, countermeasures such as creating more convenient treatment environments for patients with mental illnesses are needed (World Health Organization, 2017) .

Furthermore, cancer, especially lung and liver cancer are the leading causes of death among men and they account for half of all cancer-related deaths in Vietnam. Male liver cancer has indicated an increasing trend in recent years. Meanwhile, lung, liver, breast, and stomach cancers are the leading causes of death among women at a similar frequency (World Health Organization, 2014) .

About 73% of deaths in Vietnam are due to chronic diseases, out of which 33% are due to cardiovascular diseases and 18% due to cancer, which together account for approximately half of all deaths. The rising prevalence of lifestyle disorders such as hypertension and diabetes is also a problem, and there are surveys indicating that 20.7% of the Vietnamese population has been diagnosed with hypertension, while 41.8% of people are at risk, with the number of diabetics also doubling over the last 10 years (Do HT *et al.*, 2015; World Health Organization Western Pacific Region, 2016) . In addition, the local interviews conducted during this investigation revealed that childhood obesity (children of wealthy people in the urban areas) has been increasing in recent years, and morbidity from lifestyle disorders after these children become adults is a source of concern.

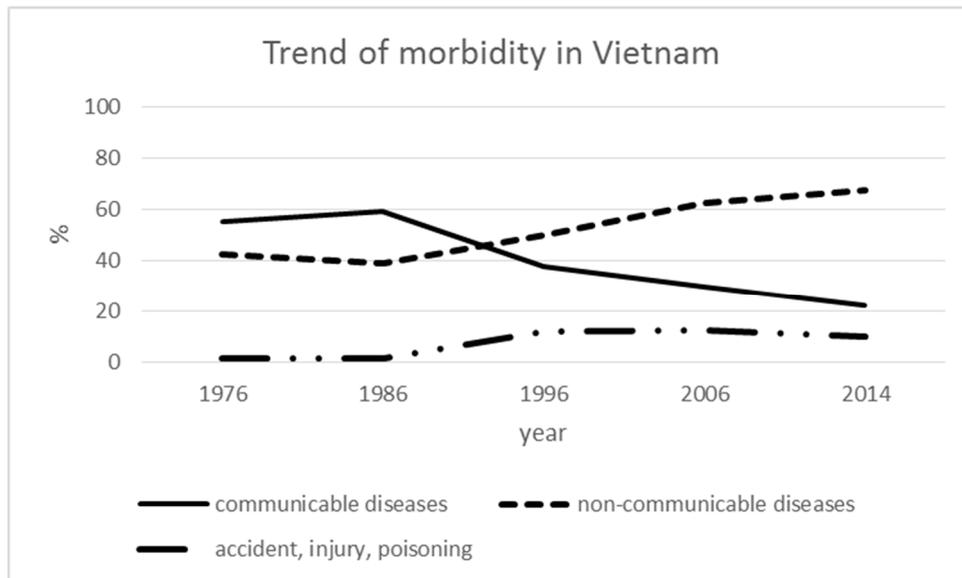


Fig. 2. Shifts in the trends of morbidity and mortality in Vietnam (Ministry of Health Vietnam, 2014)

(3) Concentration of patients at large hospitals

One particularly problematic healthcare issue in Vietnam is the concentration of patients in large hospitals in urban areas. An average of 4,000 outpatients visit Bach Mai Hospital (2,800 beds), a national hospital located in Hanoi, each day. Although the situation is alleviated by the hospital operating as an outpatient clinic in the mornings on weekends, from 05:00 onwards, there were numerous instances of severe congestion until a few years ago and patients experienced a waiting time of up to 2 days until they received an outpatient examination. A reason for this situation is the concentration of highly trained medical staff and medical facilities in large hospitals in the urban areas.

(4) Standardization of medical personnel qualifications

In Vietnam, there is no national qualifying exam for doctors or other medical staff. As there is no standardized exam, universities and the like that train medical staff vary in the curricula they use to educate people who choose these professions. At present, preparations for the introduction of national exams are underway with the aim of standardizing the qualifications of medical professionals. As a starting point, a nursing qualification system will be introduced in 2020, followed by a national examination system for doctors.

The disparity in the quality of urban and rural healthcare staff in Vietnam is also a problem, and to raise the quality of healthcare staff in these areas, large hospitals in urban areas such as Bach Mai Hospital offer training opportunities. By educating the staff of smaller hospitals about techniques and tools used in more advanced hospitals, it is possible to raise the sophistication of treatments offered at rural hospitals and reduce the concentration of patients in large urban hospitals.

There are also assistant-level staff members who only receive short training for co-medical positions such as pharmacists and nurses.

(5) Access to medicines

Inadequate use of medicines is common due to the insufficient national programs and regulations concerning access to drug products in Vietnam. In particular, many prescription drugs can be purchased without a prescription in Vietnam, and if a patient suffers from some form of disease, two-thirds of the patients do not undergo any medical examination by a doctor and attempt to treat themselves through “self-medication,” in which case they purchase over-the-counter remedies at a pharmacy (Babar ZUD, 2017) . In particular, despite needing a doctor’s diagnosis and prescription for dispensation, antibiotics have become the most sold drugs at pharmacies. Such methods of obtaining antimicrobials often involve a lack of drug information, leading to inappropriate use (Chuc NT *et al.*, 1999) . In addition, pharmacies in Hanoi seem to sell omeprazole, which controls inflammation in multiple conditions, such as suppressing steroid drug abuse and steroid-related side effects.

Although Vietnam has achieved remarkable economic growth and improved access to medicines in recent years, it is hard to claim that the problem of access to medicines in the poorest rural areas has been fully resolved. There are abundant medicines covered by insurance in the inventories of relatively large hospitals, but rural medical facilities often run out of various medications that are used frequently. As a result, rural patients are compelled to pay more for drugs sold at private pharmacies.

(6) Drug costs

In Vietnam, 72% of the total expenses on drugs account for patients’ out-of-pocket expenses, out of which 58% comprise of drug purchases without a prescription, while 14% comprise of patient-borne costs for prescription purchases. In addition, 17% of these costs are insurance payments for medicines prescribed by hospital physicians, 5% are public expenses for diseases such as tuberculosis, HIV/AIDS, and epilepsy, and 6% are costs paid by other parties (Babar ZUD, 2017) . Therefore,

in Vietnam, purchasing outpatient medications, even with a prescription, involves patient's out-of-pocket expenses. (Figure 3)

Universal Health Coverage (UHC) is being promoted in Vietnam. However, the population has not been fully covered yet, as the national insurance coverage rate was 72% in 2015. The social insurance counter and the self-paying counter are separated, with the former taking a very long time, thus making redemption procedures complex. This, together with the purchase of prescription drugs without a prescription, is a factor that raises the out-of-pocket drug expenses rate in the country.

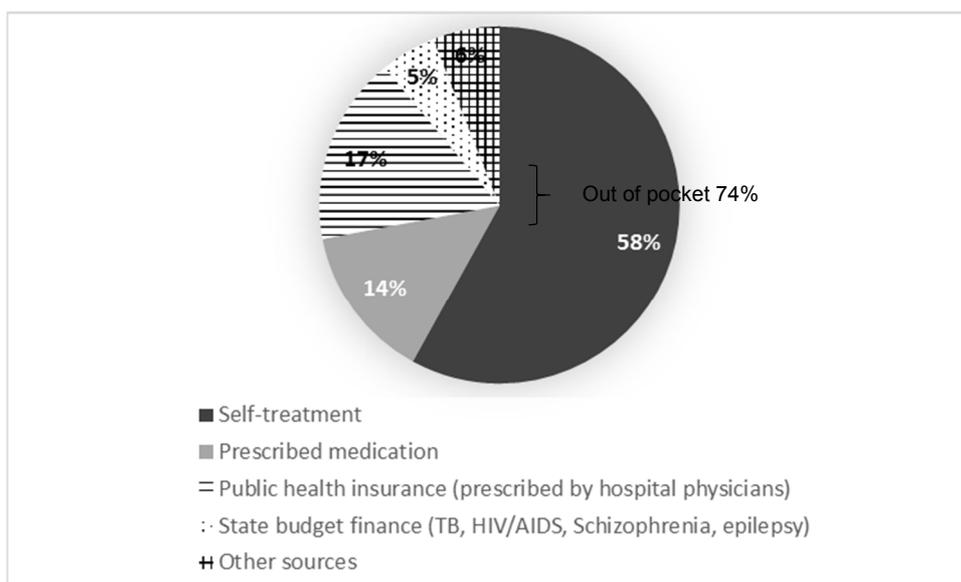


Fig. 3. Breakdown of drug costs (Babar ZUD, 2017)

(7) Drug pricing

According to a study conducted in 2005, the prices of drugs in Vietnam were relatively high, with their official prices being 46.58 times the international reference prices. Further, the price of the most inexpensive generic drug is 11.41 times the reference price (Nguyen AT *et al.*, 2009). However, this situation has gradually improved and as of 2011, generic drugs have been priced according to their corresponding international reference prices.

In addition, a reason for the high drug prices in Vietnam is related to public medical institutions being more expensive than private ones (Nguyen AT *et al.*, 2009). Another reason is the exclusive sale of the original product which involves bribing the prescribing doctor's hospital procurement manager for generic products (Nguyen AT *et al.*, 2017).

Health sector reforms since 1989 have transformed Vietnam's health care system from a publicly funded and provided health care system to public-private mix. With the shift towards a market economy, Vietnam has allowed pharmaceutical companies to set prices of their products based on market forces, subject to stabilization by the State. As for the drug price, the bid price is currently the redemption price in hospitals, while the sum of the bid price and the margin (1.5 to 7.5%) is the selling price in pharmacies. A number of legislative and regulatory reforms have been introduced to regulate medicine prices in Vietnam, which were intended to ensure transparency of prices along the supply

chain, through price declaration and publication of price information. The initiatives, however, have been less successful than expected because they did not address the need for reasonable prices or the need to differentiate between declared, published and selling prices. Further, provisions were not routinely monitored or effectively enforced. (Babar ZUD, 2017)

(8) Generic drug products

As of 2017, approximately 40-50% (amount basis) of the drugs used in Vietnam are generic drugs. Comparing the price per tablet of a medicine (amlodipine 5 mg) sold at pharmacies with the price of their generic equivalent revealed that the former is priced at 8,000 Vietnamese dong (~40 yen), while the latter is only 800 Vietnamese dong (~4 Yen), thus indicating a tenfold increase.

A policy implemented in 2008 in Vietnam mandates doctors to write the generic name of the drugs in their prescriptions. However, despite the absence of incentives to prescribe generic drugs, which is due to their non-uniform composition, the rewards received by prescribing doctors and the staff overseeing drug procurement are a factor impeding the spread of generics (Babar ZUD, 2017) .

(9) Drug quality (counterfeit drugs, Good Manufacturing Practices (GMP))

In Vietnam, a quality inspection (bioequivalence and dissolution tests) of drug products is conducted annually by the Ministry of Health to ensure quality. A total of 30,000-40,000 samples of drugs are randomly selected from various sources throughout the country (Babar ZUD, 2017) . In a given year, this inspection reveals that approximately 3% of the drugs are of insufficient quality, while 0.1% of them are counterfeit. However, there are positive and negative aspects of these figures. Regulating and monitoring the inflow of smuggled goods near the Chinese, Laotian, and Thai borders is particularly difficult. This suggests that these figures can be much greater.

As regards drugs produced in Vietnam, we surveyed 178 pharmaceutical companies that had obtained WHO GMP certification in 2011, and also observed variations in the quality of samples.

(10) Measures to promote appropriate use of medicines (adverse event reporting and educational programs to promote drug safety)

Data on adverse drug events in Vietnam is compiled in bulk at the Hanoi Medical College in the north and the Cho Ray Hospital in the south. Our interview revealed approximately 300 adverse reaction reports at the Bach Mai Hospital and approximately 1,000 reports submitted from the entire northern region.

In addition, guidelines to promote pharmaceutical safety at national hospitals in Vietnam such as the Bach Mai Hospital as well as development programs for nurses and pharmacists involving the proper use of medicines in places like the ICU are being prepared. These attempts aim to prevent accidents caused by medicines and increase the number of co-medical staff capable of providing high-level care.

(11) Vaccines

In the “Immunization Expansion Plan” that Vietnam has been conducting since 1981, the state has listed six vaccines that the citizens are required to receive (measles, polio, diphtheria, pertussis, tetanus, and tuberculosis). It has also promoted the domestic production of vaccines. JICA is actively involved in this plan and a measles vaccine manufacturing facility was constructed between 2003 and 2006 using grant funding, with the facility and its equipment maintaining compliance with the WHO quality management standards (GMP). Furthermore, from 2006 to 2010, Japan transferred the measles vaccine manufacturing technology conforming to WHO’s GMP standards in the first stage of technical operations of a measles vaccine manufacturing technology transfer project. Currently, this project has entered its second phase and will continue as a technology transfer project for combination vaccine manufacturing in addition to the measles vaccine (Japan International Cooperation Agency 2016; 2013; 2009) .

(12) Issues concerning drug-resistant microbes

The incidence of drug-resistant microbes in Vietnam is higher than in its neighboring countries, and it is regarded as the country’s top priority (Changa YT *et al.*, 2017; Hoang PH *et al.*, 2017) . Drug-resistant microbes are not only a problem in Vietnam, as they can also spread to neighboring countries through the migration of people. WHO and other nations are also providing support. The reasons for issues related to drug-resistant microbes in Vietnam include circulation of poor quality (formulations with less than the standard dose) antibiotics, poor in-hospital infection controls, frequent trading of antimicrobials without prescriptions, excessive use of antibiotics in the agricultural sector (Nguyen TN *et al.*, 2016) , and low monitoring capacity of resistant microbes. Many resistant microbes are believed to have originated from the excessive use of antibiotics in agriculture as they have been found in soil and water resources (World Health Organization, 2015) . Further, it is frequently observed that Vietnam, like other countries, lacks public awareness of antimicrobial drugs, which has resulted in behaviors such as discontinuing antibiotic use before the end of a prescribed dosing period, thus leading to the rise of resistant bacteria. In addition, healthcare workers often have insufficient knowledge; for example, the administration of ceftriaxone for 30 days to prevent infection in inpatient cases.

As a countermeasure against resistant bacteria, the Ministry of Health has prepared guidelines for the use of antibiotics by medical staff. It also offers educational programs aimed at improving public literacy.

2) Potential for pharmaceutical industry development (opportunities and risks)

(1) Market attractiveness and points of concern

With regard to information concerning future opportunities and risks in the Vietnamese market, the government has declared that 75% of its expenditure will be reallocated to domestically-produced generics. State-procured medicines are mainly supplied to public medical institutions such as national hospitals and as such, care must be taken. However, as mentioned above, the market for anticancer

and chronic disease drugs in Vietnam are expected to continue growing, and there is a need for therapeutic drugs in these areas even though they are generics.

Although not considered as medical products, Vietnam has been witnessing a boom in the health food industry, particularly with the rising demand for Japanese health food products due to their reputation of reliability. This observation may also present opportunities, as it is indicative of a high level of investment awareness with respect to wellness and medical care.

(2) Patents

Vietnam is a member of the World Trade Organization (WTO) and joined the Trans-Pacific Partnership (TPP) in 2016. Vietnam also has a law governing intellectual property. The National Office of Intellectual Property (NOIP) is the entity with jurisdiction over intellectual property in Vietnam, and expert staff conduct its operations (National Office of Intellectual Property of Vietnam, 2017) .

One public health issue related to patents in Vietnam is patent linkage, that is, when approving generic drugs, it is necessary to inform the original drug manufacturers and build advance coordination with it to prevent unstable product supply due to issues such as litigation. This rule leads to the protection of the market shares of leading pharmaceutical manufacturers and as stated previously, the higher prices of Vietnamese pharmaceuticals vis-à-vis its neighboring countries. Further, the issue of medication access in poor rural areas is yet to be solved. Under such circumstances, it is feared that an arrangement that makes obtaining generic drugs more difficult will further complicate the issue of access to medicines in Vietnam.

As regards patents, patent information often leads the problem of imitation products in the market. However, this problem does not seem to have become significant at present. As such, companies should carefully monitor how information is managed outside their factories during the manufacturing process.

(3) Human resource procurement

Vietnam has a high literacy rate of 94.5% among residents who are 15 years or older (2015). In addition, according to testimonials obtained in local interviews, Vietnamese workers are diligent and serious. In particular, it is believed that Vietnam faces minimal issues in securing workers for manufacturing positions. However, in recent years, it has become an attractive nation for other industries, thus creating a synergy between newly established factories and the talent pool. Moreover, the flow of top talent from overseas is not limited only to Vietnam, but occurs in other nations as well.

One issue regarding entry into Vietnam is finding key people who are familiar with the local business climate; such people are often employed at wages similar to those offered in Europe and the United States.

(4) Expectations for Japanese businesses

Currently, the entry of Japanese pharmaceutical companies into Vietnam has been slow. During the

interviews conducted for this investigation, each participant was asked the following questions. What is expected of Japanese pharmaceutical companies? How can Japanese pharmaceutical companies highlight their presence? We received the following answers:

1. Sponsoring pharmaceutical-related conferences and symposia
2. Offering themes for study groups of healthcare personnel
3. Providing scholarship opportunities to promote the professional development of healthcare personnel

Sponsoring pharmaceutical-related conferences and symposia has already been attempted by Western-affiliated pharmaceutical companies and they appear to be successful in their efforts. The study groups for healthcare professionals refer to workshops focusing on topics such as lifelong education; however, there is little opportunity to obtain information regarding the latest medical products and techniques in Vietnam. Moreover, the support of generic drug companies is also required. Finally, as regards the scholarship opportunities for professional development, such programs are expected to be implemented and they will be particularly helpful for poor rural areas that face severe shortages of medical personnel.

5. Discussion

This was an investigation of (1) the status of appropriate use of pharmaceuticals and the adverse event/drug quality monitoring framework in Vietnam and (2) the need for capacity building (including human resource development) in fields related to pharmaceuticals, to shed light on the opportunities and challenges facing pharmaceutical companies currently operating in Vietnam as well as those that are considering entering this market in the future.

Vietnam appears to be an attractive market for pharmaceutical companies and other healthcare businesses due to the rapid aging of its population and remarkable economic growth. However, income disparity in this region is still significant, and the section of the population capable of affording costly new drugs is currently small. However, given the incidence of chronic diseases such as cancer and other lifestyle diseases as well as the increase in mortality rate, the demand for pharmaceutical products in Vietnam is highly likely to increase in the future. Moreover, Vietnamese people are a health-conscious people, and wellness-related sectors such as health foods may also witness heavy demand along with pharmaceutical products.

The quality of pharmaceuticals in Vietnam is not uniform. Although the Vietnamese Ministry of Health regularly conducts drug quality inspections, it is facing difficulties in controlling the supply and distribution routes that lie outside the regular supply chain (e.g., agent entities of pharmaceutical manufacturers). Further, gaining an understanding of the quality of drug products smuggled in from neighboring countries is another challenge. Moreover, the quality of drug products manufactured domestically in compliance with the GMP can also fluctuate; hence, establishing a quality monitoring and management framework is necessary.

As regards drug product safety, the system governing adverse event reporting in Vietnam is primarily facilitated by major hospitals. However, at present, it is not capable of providing sufficient information to enable a holistic understanding of the overall prevalence of a given side effect in the region. One reason for this is that the staff working at pharmacies in this region is often referred to as “assistant pharmacists” who have received only a short training. Another reason is that, similar to Japan, pharmacies in Vietnam are positioned as components of larger medical institutions. It is expected that the lack of information on patients’ drug purchase history will result in the inability to manage medication use and prescription adherence. In the future, training human resources capable of overseeing regional pharmaceutical safety and implementing oversight systems will be necessary.

Based on the results of this investigation, it was found that the purchasing and selling of prescription medications at regional pharmacies without prescriptions is permitted in Vietnam, a characteristic shared with various neighboring Southeast Asian countries. This situation can lead to easy access and use of steroids and antibiotics, which raises concerns regarding side effects of drugs and the spread of resistant bacteria. With regard to the issue of drug-resistant microbes, currently, Vietnam only has weak surveillance systems in place to ascertain the extent of microbial resistance. Thus, in addition to promoting the proper use of antimicrobial drugs, establishing microbial resistance test methods that can be conducted with the limited medical facilities and staff in Vietnam is also an urgent task. Conducting more detailed investigations of methods to ensure patient safety in the absence of physician diagnoses and prescriptions is of course necessary in developed nations as well.

Vietnam has not established a national qualification exam for medical staff. Further, knowledge and skill requirements in this field are not standardized. Some pharmacists and nurses are involved in the operation of practical training programs at vocational schools, and the quality of medical services can vary. The demand for therapies for lifestyle diseases and anticancer drugs is expected to rise in the future; hence, the personnel working with these products must have advanced medical knowledge, such as the competency to provide guidance to patients undergoing complex treatment regimens and respond appropriately to serious side effects. Accordingly, there is an urgent need to develop these competencies in healthcare staff and ensure their proficiency with the use of such treatments. Furthermore, these human resources are expected to be able to contribute not only to hospital activities but also to regional pharmaceutical safety. To train the medical personnel involved with more specialized medicines, pharmaceutical companies will need to support the development of excellent human resources through programs such as scholarships along with sponsoring study groups and academic symposia geared towards the professional development and education of healthcare staff.

6. Conclusion

Vietnam is experiencing both rapid economic growth and aging of its population, making it a very attractive country for the pharmaceutical industry. However, the country faces problems that are not faced by developed countries, such as providing access to medicines despite income disparity and maintaining drug safety and quality. Pharmaceutical companies considering entering the Vietnamese market should avoid acting only as suppliers of medicines and should instead strive to offer more

comprehensive services such as advancing the appropriate use of medicines (fostering the development of human resources capable of leading efforts to ensure drug quality and promote proper use.)

7. Acknowledgements

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