Chapter 5
Pharmaceutical Policy in Vietnam

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Abstract Health sector reforms since 1989 have transformed Vietnam's healthcare system from a publicly funded and provided healthcare system to public–private mix. With the shift toward a market economy, Vietnam has introduced several market-oriented measures including the introduction of user fees, legalization of private pharmacy and medical practices, and liberalization of the production and sale of pharmaceuticals. Private pharmacies have become the dominant medicines supplier in the market. At the same time, the provision of free medicines dispensed through the public health system was discontinued. Spending on medicines, user fees, and increased autonomy for health facilities and healthcare providers led to substantial increases in out-of-pocket health expenditure. Because of high medicine prices, poor quality of medicines, irrational selection and use of medicines, unsustainable pharmaceutical production and distribution systems, and a lack of a financial support system for drug procurement, access to the right medicines at the time people need them remains a major challenge for the majority of the population.

A number of legislative and regulatory reforms have been introduced to address the side effects of the market economy on access to essential medicines. The initiatives, however, have not been able to keep up with the rapid changes in the health and pharmaceutical sectors. Furthermore, the provisions were not routinely monitored or effectively enforced.

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5.1 Introduction

From the perspective of key indicators of health outcomes such as child and maternal mortality, Vietnam has achieved standards similar to those found in much wealthier countries [57]. However, Vietnam's healthcare system is deemed to be weak in the distribution of health attainment across regions, income groups and medical conditions [50, 57]. The gap in health outcomes between the rich and the poor has widened, especially with respect to child survival [57]. A large proportion of health spending is financed by out-of-pocket patient expenses [53], although the Vietnam government has initiated reforms aimed at redressing this imbalance, including subsidization of the poor and expansion of public health insurance [57].

Medicine expenditure accounts for a large component of total healthcare costs. In 2005, Vietnam spent USD 3.18 billion on health (USD 1 = VND[1] 15,907.00), of which 53.3% was for medicines, an almost threefold increase in absolute terms from 2000 [52]. Rising prices for medicines have been reported to account for most of this increase [57]. From 2003 to 2004, prices of some medicines soared fourfold [4], and the medicine and health component of the consumer price index (CPI) increased by 13.8%, almost double the CPI [22]. Medicines play a crucial role to improve health outcomes. However, they have become unaffordable for the lowest paid unskilled government worker, thus being unaffordable for the large percentage of the population who earn less than this benchmark [38]. Pharmaceutical policy reform is therefore central to current efforts to improve Vietnam's healthcare system.

This chapter aims to analyze the pharmaceutical policy in Vietnam to identify scope for improvement. It begins with an overview of Vietnam's health system and pharmaceutical situation. A section follows on regulatory environment, highlighting the function of Vietnam's medicines regulatory authority, the drug quality control system, the pharmacovigilance and situation of substandard, and counterfeit medicines in the country. This chapter continues with sections on the supply system, financing and use of medicines, analyzing the causes of the dysfunction within the pharmaceutical sector, as well as the issues impacting on rationale medicines use in the country. This chapter ends with conclusions and recommendations to move forward.

5.2 Vietnam Health System

Vietnam's healthcare system has evolved from health systems established separately in North and South Vietnam. During the war period (1945–1975), North Vietnam established an extensive network of primary healthcare facilities with the aim of achieving universal healthcare coverage. In urban areas, nearly 100% of the

[1] Vietnam Dong: Vietnamese currency.

population were covered, as were 75% of the population in rural areas [54]. In South Vietnam, a strong private health sector dominated until, upon unification with the North in 1975, private enterprises were banned [25].

Post 1975, Vietnam suffered severe financial pressures, including costly postwar reconstruction, an economic blockade by the United States, withdrawal of aid from the former Soviet Union and a rising inflation rate [6, 54, 55]. This had significant impacts on the healthcare system. The expansion of the network of free public health services that had been set up in North Vietnam to include the South added further economic strain, resulting in poor maintenance of healthcare facilities and lack of basic equipment and medicines in many health stations and hospitals [54]. At this time, the domestic pharmaceutical industry was only able to meet 30% of the population's demand for medicines, and most essential medicines had to be imported, as there was no capacity to manufacture in country [55].

The economic reform process known as "DoiMoi", initiated in 1986, led to important policy shifts in the healthcare system in the late 1980s and early 1990s. A number of market-oriented measures were implemented, including the introduction of user fees at public health facilities, legalization of private pharmacy and medical practices, and liberalization of the production and sale of pharmaceuticals [51]. Free access to healthcare was gradually replaced by a system of direct payment by patients [25]. The provision of free medicines dispensed through the public health system was also discontinued [25]. As a result, Vietnam's near-universal, publicly funded and provided health services were converted into an unregulated public–private mix [44].

One result of the country increasing its reliance on market mechanisms was substantial increases in consumer's out-of-pocket (OOP) health expenditure [57]. Between1995 and 2008, OOP expenditure ranged from 55 to 66% of total health expenditure [53]. The rising household OOP spending on health was partly because of increasing user fees in public hospitals [37]. Increases in medicine prices also contributed to the growing magnitude of absolute household OOP expenditure on health.

To address the growth in OOP payments that placed financial barriers to healthcare access, the government issued a national Health Insurance Decree in 1992, introducing compulsory health insurance for people in salaried employment. Since then, health financing from social health insurance as a percentage of public health expenditure has risen, from 7% in 1995 to 32% in 2008 [53]. In 2008, the Health Insurance Law was passed and came into effect in July 2009. The law stipulated that the government was responsible for fully subsidizing health insurance for children <6 years of age, the elderly, and the poor, and for partially subsidizing health insurance for the near-poor and students. The law also provided a road map for universal health coverage. By 2011, healthcare coverage in Vietnam exceeded 64% of the population [46]. Medicines eligible for public health insurance reimbursement are limited to medicines listed on the basic schedule issued by the Ministry of Health (MOH). The current schedule comprises 900 Western medicines and 57 radioactive substances and marking compounds [35]. The public health insurance scheme does not cover medicines that are purchased at private retail pharmacies.

5.3 The Pharmaceutical Situation

The health sector reforms, introduced since 1989, have also impacted on Vietnam's pharmaceutical supply chain, shifting it from a centrally controlled system to a market-oriented system [25]. The opening of the country to foreign trade and the liberalization of rules governing pharmaceutical manufacture, sale, and distribution led to a 300% increase in medicine production and a tenfold increase in importation of medicines between1988 and1992 [54]. To improve coordination of pharmaceutical policies, the National Drug Policy was promulgated in 1996, with two basic goals: ensuring regular and adequate supply of good-quality medicines at affordable prices, and ensuring rational use of medicines [21].

To facilitate the implementation of the National Drug Policy, the Drug Administration of Vietnam was established in 1996 with responsibility for state management of pharmaceuticals [20]. The Drug Administration of Vietnam adopted a road map of good practices to ensure the quality of medicines across all aspects of the supply chain. In Vietnam, manufacturers have to comply with the code of Good Manufacturing Practice (GMP), importers with Good Storage Practice (GSP), distributors with GSP and Good Distribution Practice (GDP), and retailers with Good Pharmacy Practice (GPP).

Vietnam's pharmaceutical market is, however, heavily dependent on imports. Imported medicines account for more than 50% of the market share, focusing on specialized products. By the end of 2011, there were 15,552 imported medicines covering 971 active substances, averaging 16 brands per active substance [36]. The range of imported products is wider than those locally produced, and there is trading duplication of some active substances. For example, one substance, cefixim, had 458 imported brands with a valid registration number in Vietnam by 2011 [36].

Domestic medicine production accounts for an increasingly growing market share, rising from 36% in 2001 to approximately 50% in 2011, reaching USD 1.14 billion [36]. However, the domestic pharmaceutical industry is characterized by limited R&D facilities, insufficient financial capacity, and poor management [2]. Most local pharmaceutical manufacturers comprise small-scale operations with outdated manufacturing technology and duplicated production processes. About 90% of the raw materials used in domestic production are imported [5], thus making domestic medicine prices subject to price fluctuations in international prices, as well as fluctuations in the exchange rates. Nearly 95% of imported active pharmaceutical ingredients are antibiotics, vitamins, antipyretics, analgesics, and antispasmodic drugs [31], reflecting a concentration of domestic pharmaceutical production on only some therapeutic classes. By the end of 2011, there were 13,268 locally produced medicines, representing 524 active substances registered for sale in Vietnam, averaging 25 locally produced brands per active substance. Thus, local manufacturers compete for a very limited, and often uneconomic, market share, an example being 1044 registered products for one medicine, paracetamol, by 2011 [36].

5.4 Regulatory Environment

5.4.1 Medicines Regulatory Authority

The Drug Administration of Vietnam (DAV) on behalf of the Ministry of Health is the medicine regulatory authority in Vietnam. The DAV is responsible for state management of pharmaceuticals. It includes developing pharmaceutical legislation and regulations; registering medicines; issuing, suspending, or withdrawing drug import–export licences and certificates of GMP, GSP, good laboratory practice (GLP), and good agricultural and collection practice (GACP) for medicinal plants; controlling pharmaceutical manufacture, importation, pricing, promotion and advertising, and pharmacy practice. The DAV also carries out postmarketing surveillance and pharmaceutical inspection in collaboration with the National Institute of Drug Quality Control and the MOH Pharmaceutical Inspection at central level. At provincial level, there is often a unit of pharmaceutical management within the provincial health department assisting provincial health department executives in implementation of state management of pharmaceuticals in the provinces.

Most medicines must have product registration, as indicated by a valid registration number, prior to marketing in Vietnam. The MOH can allow medicines without a registration number to be marketed on a case-by-case basis, to avoid shortage of medicines. By law, within 6 months from the date of receiving complete and legitimate registration applications, the MOH shall issue medicine marketing authorization for the medicine. To ensure the quality, efficacy, and safety of medicines marketed, the pharmaceutical manufacturer must meet the GMP standards and the products must pass laboratory quality testing and clinical trials either in Vietnam or in exporting countries. Where applications fail to meet relevant requirements, the MOH will release written reasons for refusing registration [34]. By the end of 2011, there were 28,820 medicines registered in Vietnam [36].

5.4.2 Quality Control

A system of drug quality assurance/quality control (QA/QC) has started since 1957 with the establishment of the Drug Quality Control Department under the MOH, which later became the National Institute of Drug Quality Control of Vietnam (NIDQC). After the unification of the North and the South, in 1977, a Sub-Institute of Quality Control in Ho Chi Minh City was established under the administration of the NIDQC for drug quality control in southern provinces. Currently, the drug QA/QC system includes NIDQC, Ho Chi Minh City Sub-Institute of Quality Control, and 61 drug quality control laboratories of the provincial health departments [36].

Drug quality control is regulated by the Circular 09/2010/TT-BYT of the Ministry of Health of Vietnam. It stipulates quality control areas including development, issuance, and implementation of drug quality standards; management of drug

quality testing in pharmaceutical production, import–export, distribution, and use; and processes for suspending medicines from circulation, withdrawing, and destroying medicines not meeting the quality standards. *Vietnam Pharmacopoeia*, currently in the 5th edition, stipulates the national standard of medicines and methodologies for testing drug quality.

Vietnam aims to ensure the quality of medicines throughout the supply chain, first through a series of good practices including GMP, GSP, GDP, GPP, GACP, and GLP. However, the inadequate number of pharmaceutical inspectors leads to weak, irregular inspections of manufacturers and ineffective inspections of distributors' premises. It was reported that some private pharmacies had been tampering with labels, selling, and dispensing medicines with unknown origin and even counterfeit medicines [56].

Second, the postmarketing surveillance is in place with random quality testing of about 30,000 samples, bioequivalent testing of about 20 medicines, and solubility testing of 50 substances being conducted by the QA/QC system, annually. The QA/QC system has capacity to provide analytical services and quality testing for most essential medicines in Vietnam. However, the system faces difficulties in testing new active pharmaceutical substances, new pharmaceutical formulations, biological products, or high-tech medicinal products. This is because of the limited investment to the system from state budget. While the NIDQC and the Sub-Institute are well equipped, provincial laboratories have basic equipment only, and some still lack essential equipment of high-performance liquid chromatography and drug solubility testing machine [36].

5.4.3 Pharmacovigilance

In 1996, Vietnam established two adverse drug reaction (ADR) centers in Hanoi and Ho Chi Minh City to gather ADR reports throughout the country. The circular 08/BYT-TT of 04/07/1997 on regulating the organization, responsibility, and function of hospital Drug Therapeutic Committees then stipulated the establishment of drug information unit in each hospital, as well as requirement for ADR reporting. In 1999, Vietnam became the 55th member of the global ADR network, and ADR reporting has become an official indicator for annual assessment of hospitals since 2009. In 2009, a National Drug Information and ADR Centre was also established in Hanoi University of Pharmacy, Hanoi, and 2 years later, a South Vietnam Drug Information and ADR Centre was established in Ho Chi Minh City. The number of ADR reports continue to increase, from 519 reports in 2001 to 2407 in 2011, nationally [36].

The pharmacovigilance activity, however, is challenging because of an incomplete drug information network from central to local level that lacks coordination throughout the system. The most challenging hurdle is a lack of human resource with many district hospitals not having advanced pharmacists (i.e., those with a university level), who are competent and have sufficient knowledge in drug

information and ADR. Drug information units in hospitals are often not properly invested, and hospital executives often underestimate the importance of drug information and ADR work [36]. Hospital pharmacists mainly fulfill their logistic task of procuring and dispensing medicines rather than clinical function.

5.4.4 Counterfeit Medicines

Law on Pharmacy No. 34/2005/QH11 defines counterfeit medicines as products manufactured in any form of a medicine with a deceitful intention, and falling into one of the following cases:

(a) Counterfeit medicines have no pharmaceutical ingredients.
(b) Counterfeit medicines have pharmaceutical ingredients, which are, however, not at registered contents.
(c) Counterfeit medicines have pharmaceutical ingredients different from those listed in their labels.
(d) Counterfeit medicines imitate names and industrial designs of medicines which have been registered for industrial property protection of other manufacturing establishments.

The law prohibits trading counterfeit medicines. Those committing this prohibited act shall be imposed a fine in accordance with the Government Decree No. 185/2013/ND-CP on providing the penalties on administrative violations in commercial activities, production of or trading in counterfeit or banned goods, and protection of consumer rights. They might even be sentenced to a term of imprisonment according to Vietnam Penal Code.

There are limited data on the extent to which counterfeit or substandard medicines circulate in Vietnam. The postmarketing surveillance of medicines in circulation by the QA/QC system has discovered a number of substandard or counterfeit medicines. Table 5.1 shows the rate of substandard, counterfeit medicines in random sample quality testing from 2006 to 2011.

Table 5.1 Rate of substandard and counterfeit medicines during the period 2006–2011

	2006	2007	2008	2009	2010	2011
Substandard Western medicine overall (%)	3.18	3.30	2.90	3.33	3.10	2.81
Domestically produced medicines (%)	3.52	3.04	2.94	3.21	2.94	2.74
Imported medicines (%)	1.59	5.75	2.30	4.47	4.32	3.22
Substandard traditional medicines (%)	11.55	10.80	8.00	9.13	9.82	6.09
Counterfeit medicines (%)	0.13	0.17	0.10	0.12	0.08	0.09
Number of samples (n)	29,819	25,460	29,490	31,542	28,816	35,508

Source: MOH of Vietnam [36]

5.5 Medicines Supply System

Pharmaceutical supply chain in Vietnam is a complex system, which involves a number of intermediaries between manufacturers and consumers, including:

- 180 domestic pharmaceutical manufacturers (including 22 Foreign Direct Investment (FDI) producers), 90 importers, and 800 domestic wholesalers/distributors [14]
- Three FDI enterprises investing in drug logistics [14]
- 438 foreign pharmaceutical companies [14]
- 39,172 retail medicine outlets, including 9066 private pharmacies [14]
- 13,460 public healthcare facilities, including 974 hospitals, 781 regional polyclinics, and 10,917 commune health stations [23]
- 74 private hospitals and more than 30,000 private health clinics [37]

Figure 5.1 shows a schematic representation of the current pharmaceutical supply chain in Vietnam. Locally produced medicines from Vietnam's pharmaceutical manufacturers can be distributed directly to retailers and healthcare facilities or indirectly through wholesalers or distributors. Vietnamese manufacturers holding a retail license are able to supply medicines directly to end-users. Classified as domestic pharmaceutical producers, Foreign Direct Investment producers can directly distribute the products that they manufacture in Vietnam.

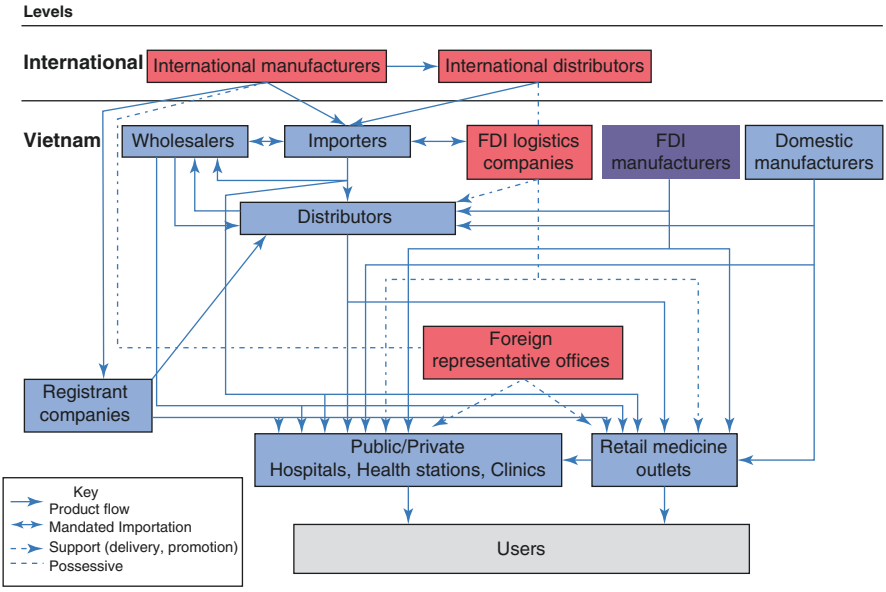

Fig. 5.1 The pharmaceutical supply chain in Vietnam. *FDI* Foreign Direct Investment (*Source: authors' analysis*)

Foreign Direct Investment logistic companies and foreign pharmaceutical companies are not permitted to distribute pharmaceutical products directly in Vietnam. Their products have to be sold to domestic pharmaceutical distributors for distribution. Foreign distributors are only permitted to supply their medicines to a local importer. Foreign pharmaceutical manufacturers with a trading license in Vietnam who are not established in Vietnam as a Foreign Direct Investment producer can supply their medicines via their local registrant company or a local importer [33] (see Fig. 5.1).

The medicine procurement system has been decentralized to provincial level and individual health facility level. Joint Circular No. 01/2012/TTLT-BYT-BTC of January 19, 2012 required public hospitals to purchase medicines using a tendering system. The tender may be conducted by the provincial government for all hospitals in the province, or at the individual hospital level. Tender boards are responsible for drawing up the tender schedule of medicines and then deciding on successful tenders. Membership of provincial tender boards comprises provincial government officials and nominees of selected hospitals in the province. Membership of hospital tender boards often comprises the director of the hospital as chairperson, the chief pharmacist as deputy chairperson, together with senior clinical department heads and the hospital finance officer.

Tender medicines are drawn from the basic schedule, also known as the public health insurance reimbursement list, issued by the Ministry of Health. The local hospitals customize their tender in accord with the Ministry of Health basic schedule and the needs of the medical specialties offered by their clinical departments. A notional tender fee is required on the submission of both provincial and hospital tenders. Tender intervals may vary from 6 months to 1 year, and in some circumstances may be extended up to 2 years. Unlike hospital tenders, provincial tenders are let by name only, with no guarantee as to the volume of medicines that may be used. Provincial tenders have been established since 2006 with the objective being to achieve economies of scale in the tender process and also to simplify administrative processes and their attendant costs. Inpatients will be charged at hospital procurement price with no mark-up.

Outpatients can buy medicines from retail medicine outlets or hospital pharmacies. Accounting for 60–70% of retail pharmaceutical market share was more than 1000 public hospital pharmacies, and the rest 30–40% belongs to private pharmacies and other retail medicine outlets [48]. Pharmacists with a university degree and 5 years of experience can be licensed to operate private pharmacies. In remote areas, assistant pharmacists are able to apply for licenses. By law, licensed pharmacists must always be physically present when the pharmacies are open for business. In practice, licensed pharmacists are not always on duty [9].

The current pharmaceutical supply chain needs reorganization. The many layers within the distribution network, each contributing a compounding mark-up along the supply chain, serve to inflate the final price of medicines to patients. Unnecessary duplication in manufacturing, importing, and trading medicines leads to fierce counterproductive competition for an uneconomic share of an increasingly shrinking market [40].

5.6 Medicines Financing

5.6.1 Medicines Expenditures in General

Multiple policy reforms directed at mobilizing different resources for healthcare since 1989 have resulted in a fundamental transformation of Vietnam's health financing system. Vietnam's public funded health services have shifted to a mixed health financing system [44]. The structure of health financing has recently improved with a higher proportion of public health expenditure (i.e., General Government Expenditure on Health) and reduced private expenditure [37]. In 2008, the proportions of public and private health expenditure were 38.5 and 61.5% of total health spending, respectively [53].

Different existing data sources confirm that medicines account for an important share of the total health expenditure in Vietnam. Data from the National Health Account of Vietnam show that from 2005 to 2007, medicines expenditure ranges from 40 to 50% of all expenditure on health, much higher than the average of 30.4% in the low-income countries in 2006 [28]. Commercial data show a lower share for the period from 2013 to 2014 in Vietnam, yet still ranging from 32.5 to 34.4% of the total health expenditure and forecast an increasing trend for the period 2015–2019, ranging from 35.7 to 39.7% [3]. In absolute term, the total medicines expenditure increases at an average of 18% annually, growing from USD 472.3 million in 2001 to USD 2.4 billion in 2011. It makes the per capita spending on medicines increase from USD 6.0 to USD 27.7 during this period [36]. While increase in medicine consumption plays a role, rising medicine prices have been reported to contribute substantially to this increase [57].

Financing for medicines mainly comes from households' out-of-pocket payment, accounting for 72% of the total medicines expenditure, of which 58% was for self-treatment medications and 14% was for prescribed medications [36]. Increasingly important was public health insurance, accounting for 17%, whereas state budget financing and other sources account for the rest of 6% and 5%, respectively. Public health insurance pays for medicines in the MOH's main medicines schedule prescribed by hospital physicians. State budget pays for medicines in national priority programs, including free medicines for tuberculosis, HIV/AIDS, schizophrenia, and epilepsy [36].

5.6.2 Pharmacoeconomics, Medicines Pricing, and Access

Given that medicines are one of the single, largest cost components of Vietnam's healthcare system, sound medicine pricing policies are critical to keep the cost of medicine within sensible limit and improve access to essential medicines. Our previous studies have provided comprehensive analyses of the medicine pricing policy reforms and the impact of the reforms on pharmaceutical prices and accessibility

[38–40, 42]. In brief, following the shift toward a market economy, Vietnam has allowed pharmaceutical companies to set prices of their products based on market forces, subject to stabilization by the state. 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, the provisions were not routinely monitored or effectively enforced. The medicine pricing policies are still in the start-up phase, and there is currently no requirement for Health Technology Assessment to support medicine pricing [42].

The suboptimum medicine pricing regime means that medicine prices were high in Vietnam. Adjusted for purchasing power parity, the prices to patients in the public sector were 11and 47 times the international reference price for the lowest priced generics and originator brand medicines, respectively [38]. Measuring affordability as the number of days' wages needed by the lowest paid unskilled government worker to purchase a course of treatment for an acute disease or a month's treatment for a chronic disease, a worker would have had to work 0.7 days to treat an acute respiratory infection with the lowest priced generic amoxicillin (250 mg three times daily in 7 days), but would pay 15.9 days' wages with lowest priced generic ceftriaxone (1 vial, 1 g daily in 7 days) in the public sector. Medicines, therefore, were unaffordable for the lowest paid unskilled government worker, and even less so for the population who earned below this benchmark. Compared to countries in the Western Pacific Region, medicines in Vietnam were much less affordable, causing difficulty in access [38, 40].

5.6.3 Generic Medicines

Generic medicines with proven safety and efficacy represent a key strategy used by governments and third party payers to contain the cost of healthcare and improve access to existing medicines [41]. Vietnam adopted a National Drug Policy in 1996, but there were no generic medicines policies embedded. Some components of a generic medicines policy, however, have been provided in the Law on Pharmacy No. 34/2005/QH11, allowing for medicine substitution (Article 27.c) and encouraging the purchase of domestically produced medicines with cheaper prices for public procurement purposes (Article 49.2.a). The Minister of Health decision No. 04/2008/QĐ-BYT of February 1, 2008 regarding regulation on prescribing and prescription-only medicines stipulates the requirement of prescribing doctors to include the generic name on the prescription.

In 2009, an Aide Memoire on Strategic Collaboration in Pharmaceuticals was signed by WHO and the MOH of Vietnam, which mentioned a strategy to develop and promulgate a national generic medicines policy to ensure affordability of safe and quality medicines [49]. The Prime Minister Decision No. 68/QD-TT of January

10, 2014, approving the strategy for the development of Vietnam pharmaceutical sector in the period up to 2020 and a vision to 2030, also emphasizes the focus on investment to develop generic medicines production in Vietnam. However, a comprehensive generic medicines policy with strong regulatory requirements in combination with incentives for the development of the generic markets, acceptance, and rational generic medicine use has not been implemented, although it is proposed in the MOH proposal of a new National Medicines Policy for the period up to 2020 and a vision to 2030 [36].

Barriers to increasing generic medicine use include mistrust in generic medicines in terms of quality, efficacy, and safety among physicians, pharmacists, and patients. While Circular No. 44/2014//TT-BYT on regulation of medicines registration has alluded to the requirement of bioavailability and bioequivalence data regulated by Circular 08/2010/TT-BYT, there have been only 12 active substances out of about 1500 required bioequivalence data submission. Limited assessment of bioequivalence as a regulatory requirement in generic medicines registration and lack of appropriately skilled inspectors and monitoring to ensure the quality of generic medicine products contribute to the mistrust [41]. Lack of knowledge of generic medicines and misconceptions that a cheaper price equates to poorer quality also contributed to low acceptance of generics. Vietnam did not have any financial incentives to promote prescribing of generic medicines [41], whereas promotional incentives from pharmaceutical industries for prescribers to recommend more expensive branded products are prevalent. In addition, the suboptimal pharmaceutical pricing regimes led to some generic medicines being more expensive than their corresponding originator brands [40].

5.7 Medicines Use

5.7.1 Medicines Use in General

Post 1989, expenditure on medicines markedly increased. Per capita medicine consumption increased from USD 0.5 in 1986 [16] to USD 16.45 in 2008 [14]. Nevertheless, medicine consumption represents only 1.4% of Vietnam's GDP [2]. Moreover, the increase in per capita medicine consumption has not been accompanied by a rational use of medicines. Self-treatment, lack of regulation of the pharmaceutical market, and a lack of information infrastructure needed for optimal use of available resources have all resulted in the irrational use of medicines and wasteful expenditure by customers who are unable to assess their quality [9, 54].

Self-medication continues to be the most common response to illness in Vietnam. It is estimated that two-thirds of people rely on self-medication when they get sick [17, 18, 26], with private pharmacies becoming the first, and often only, contact with health services. Dramatic increases in self-medication have arisen because of laxity in pharmaceutical law enforcement. "Prescription-Only" medications are freely available for direct purchase, contrary to the law with little accompanying

information relevant to their use. Antibiotics are the "Prescription-Only" medicines, which are most frequently purchased from private pharmacies without prescription or adequate user instruction [11–13]. Use of pharmaceuticals through self-medication is therefore often inappropriate.

The Ministry of Health has issued a number of regulations relating to private pharmacy practice designed to link pharmacies into the health system. However, a lack of, or inadequate, enforcement of regulation of the pharmaceutical market, especially in the private sector, has led to medicines frequently being dispensed by unqualified staff [51]. Consequently, the quality of pharmacy services is often substandard [7].

The use of medicines prescribed by a health worker in clinics or hospitals can be problematic. The income of health workers is directly linked to prescribing patterns, both in the private sector [24] and in the public sector [51]. This has encouraged overprescribing with little concern for clinical need. Falkenberg et al. [16] found that on average, there were as many as 3.8 medicines per prescription with a high rate of injections being common. Overprescribing is also related to the lack of an information system to document medicine-related morbidity and mortality, so that health workers are not held accountable for accidents or errors in the prescribing and administration of medicines [51].

5.7.2 Essential Medicine List, Selection of Essential Medicines, and Standard Treatment Guidelines

The schedule of essential medicines and promotion of rational use of medicines was the first element of the 1996 National Drug Policy to be implemented, with the current essential medicine list (EML, established in 2013) consisting of 466 medicines. However, EMLs were not fully utilized as the basis for pharmaceutical procurement, reimbursement, or prescribing. Instead, the MOH simultaneously developed alternative expanded lists of main medicines used in public health facilities for this purpose. The current list of main Western medicines (established in 2011) contains 957 medicines/active substances, double the number of current essential medicines. Adoption of too wide a schedule of medicines, including some that are less cost-effective, counters the basic principles of an essential medicines schedule.

Hospital Drug and Therapeutic Committees (DTC) have been established, and standard treatment guidelines and national pharmacopoeia developed. Nevertheless, the dissemination of these measures, in the absence of ongoing monitoring and supervision of prescribing practices and adherence to the pharmacopoeia, has impeded achievement of the National Drug Policy goals in promoting rational use of medicines. National standard treatment guidelines need to be updated and strengthened based on the best available evidence regarding efficacy, safety, quality, and cost-effectiveness. In alignment, the current essential medicine list should be reviewed, evaluated, and revised systematically, based on the standard treatment guidelines, taking into account the current WHO model list of essential medicines and using a collaborative approach that involves all relevant stakeholders at differ-

ent levels of the healthcare system. The EML needs to be used as the basis to develop formularies for hospitals and for procurement, and reimbursement decisions made by public health insurance authorities.

5.7.3 Prescribing Behavior in General

In alignment with literature, several groups of factors were found to have been influencing the prescribing behavior of physicians in Vietnam. The first group includes factors related to the prescriber, such as physicians' knowledge, skills, attitudes, and predisposition [27, 47]. In the past, the lack of up-to-date medical knowledge led to the situation that physicians often prescribed medicines that were no longer used, or had even been withdrawn by the manufacturer as in the case of Mexaform (clioquinol) for the treatment of simple diarrhea [55]. More recent studies show that due to lack of knowledge and to protect themselves from legal issues of treatment failure, many doctors *"choose broad spectrum antibiotics"* for any infection *"to cover everything"* [40].

The second group is related to patients. There was evidence that patients sometimes demand medicines, which they believe to have better efficacy than those that are prescribed. Preference for, and/or aversion to, injections or oral dosage forms of medicine is quite common in Vietnam [16].

The third group, system factors, include pharmaceutical policies, reimbursement, formularies, practice organization, and pharmaceutical company promotion [27, 47]. Because physicians work in a regulated system, their medical practice is influenced by government policies and rules and/or regulations of the institutions and associations to which they belong. For example, in inpatient treatment blocks, prescribed medicines were limited to the hospital formulary list and the availability of medicines in hospital pharmaceutical departments. Having to seek prior approval for prescribing expensive medicines with an asterisk mark on the reimbursement medicines schedule has been also reported to deter Vietnamese physicians from prescribing those medicines [40].

5.7.4 Medicines Promotional Practices

The pharmaceutical industry with its direct marketing activities is alleged to be an influential factor in inappropriate prescribing [1, 19]. This is also true in Vietnam where the income of health workers was linked to prescribing practice [24, 51]. A comprehensive study examining the relationship between medicines promotion practices and prescribing behavior in Vietnam shows that economic survival pressures in an imperfectly competitive market forced both pharmaceutical companies and prescribers to be inextricably linked financially [40]. In many cases, this led to unethical practices in the prescribing of medicines, based on supply-driven demand for private gain, rather than on evidence-based clinical need. Individual factors such as professional ethics and personal value influenced prescribers' behaviors and their

response to inappropriate offers of informal payments. However, entrenched or intractable systemic issues including lack of transparency and accountability and poor legislative enforcement emerged as important factors perpetuating unethical practices. The magnitude of reported inappropriate behavior varied across geographical regions, sectors, and prescribers' specialties [40].

5.7.5 *Role of Pharmacist*

A large proportion of Vietnamese patients self-medicating or consulting directly with pharmacies makes pharmacies and other medicine outlets be the most frequently used healthcare facilities, accounting for about two-thirds of all health service contacts [58]. Meanwhile, the number of medicine outlets increasingly grows. In 2009, there were 39,172 medicine outlets (including 9066 private pharmacies) [14], and the number increased to more than 40,000 in 2011 (including nearly 12,000 private pharmacies) [15]. In addition to pharmacists working in private pharmacies, there are pharmacists (university or postgraduate level), intermediate pharmacists, and assistant pharmacist (secondary school level) working in pharmaceutical departments/outlets of public healthcare facilities, including 974 hospitals, 781 regional polyclinics, and 10,917 commune health stations. The GPP has been implemented following the Decision No. 11/2007/QD-BYT of January 24, 2007 to improve the quality of pharmacy services, with the role of pharmacists being not only a quality medicines supplier but also a communicator, a supervisor, and a health promoter involving ineffective medication therapy management.

In practice, although private pharmacies have grown and taken over a large proportion of primary healthcare as first-line medical care providers, the regulatory system has not been able to keep up with this rapid change [25]. Lack of human resource for monitoring and regulation enforcement means that licensed pharmacists are not always physically present when their pharmacies are open for business. Many private pharmacies, whose owners are public servants and licensed for after-working time only, still operate their pharmacies during working hours [9]. Dispensing of prescription-only medicines without a prescription is a common practice in private pharmacies [2]. Meanwhile, clinical pharmacy is fledgling, and the role of hospital pharmacists is mainly for logistics, rather than to engage in pharmaceutical care and quality use of medicines [40].

5.7.6 *Pharmaceutical Care Interventions and Assessment of Community Pharmacy Practice*

From government perspective, implementation of GPP is the only intervention to enhance the role of pharmacists in pharmaceutical care and to improve the quality of pharmacy services. However, the GPP implementation is slow. Two years after the launch of GPP, by March 2009, only 5% of private pharmacies (444 pharmacies)

met GPP standards [14]. More recent data from provincial health bureau reports show that by December 31, 2010, there were 3455 private pharmacies having been granted a GPP certificate, accounting for about 30% of the total private pharmacies in the country. One of the reasons for slow implementation of GPP in private pharmacies is that the pharmaceutical sector regulations have not been sufficiently enforced. There have been no financial benefits for private pharmacies in return for accreditation and compliance with GPP. In fact, GPP private pharmacies that are required to adhere to GPP requirements such as the convention of prescription-only medicines are disadvantaged in competing with non-GPP private pharmacies, which commonly follow no such conventions [40]. To date, there has been no study assessing the impact of GPP implementation on the pharmacy services in Vietnam.

While the government focuses on the implementation of GPP, some nongovernment organizations and researchers have examined different interventions including educational and training methods, peer influence and regulatory enforcement, or the combination of these interventions [8, 10, 32]. The authors found that providing training, especially training in combination with multicomponent interventions, improves community pharmacy practice. These intervention studies together with a number of other studies assessing community pharmacy practice in Vietnam have indicated the shortcomings in pharmacy practice in terms of questions asked, advice given, and appropriate medicines dispensed, as well as limited involvement in preventive services and a high degree of discrepancy between pharmacy staff stated intentions and practice [7, 9, 11–13, 43, 45]. One of the reasons for low quality of pharmacy service in community pharmacies is the absence of the pharmacist in charge. A study shows that in up to 76% of community pharmacies in Vietnam, the pharmacist in charge was not present during working hours [29].

5.7.7 Medicines Use Research

A few studies on medicines use in Vietnam have been undertaken. A recent systematic review on irrational use of medicines in China and Vietnam identifies 29 studies and shows that overall the medicines use research in Vietnam was of high quality (scoring 7.86 out of 10 on average), with the majority (66.5%) being cross-sectional/case–control studies [30]. Twenty-seven studies (93.2%) were peer-reviewed publications, and 62.1% were published during the period from 2009 to 2013. Much of this work studied pharmacy practice with a focus on diarrhea management, pneumonia susceptibility, and antibiotic overuse. Eighteen studies (62.1%) looked at patients and general population, while clinicians (prescribing) and pharmacy staff (dispensing) were examined at 44.8% and 31.0%, respectively. Medicines use research in Vietnam mainly used rural setting as study sites (51.7% using rural areas and 20.7% examining both rural and urban areas compared to only 27.6% investigating urban areas). Different data collection methods have been used with qualitative interviews accounting for 34.5%, population-based survey (29.4%), pharmacy survey (24.1%), healthcare facility survey (17.2%), prescription survey (13.8%),

and medical record review (3.4%) [30]. However, other existing data sources including commercial medicine utilization data (e.g., IMS Health), sale data from pharmaceutical importers, manufacturers, wholesalers, and especially reimbursement data have not been used in medicines utilization research in Vietnam.

5.8 Summary and Way Forward

Vietnam's transition from a socialist economy to a market-based economy has presented a number of challenges for its healthcare system. Free access to healthcare, including medicines, has been gradually replaced by a system of direct payment by patients. Increased reliance on market mechanisms has led to relative neglect of social mandates and a surge in healthcare costs. The government has introduced a number of pharmaceutical policies, aiming to address these challenges and increase access to affordable healthcare. Nevertheless, the regulatory system has not been able to keep up with the rapid changes in the healthcare system. In addition, the existing regulations have not been sufficiently enforced.

A range of policy measures and changes are required to improve access to medicines in Vietnam. Short-term recommendations include amendments to pharmaceutical policies, with better enforcement of current regulations. Medium-term measures include the public health insurance system taking an active role in price setting, pooling procurement through a national tendering procurement system, and reform of the domestic market through rationalization with appropriate capital and technological investment to achieve improved efficiencies and economies of scale. Long-term goals include health system improvements to address poor governance, low remuneration of prescribers, with additional measures to limit the scope for corrupt practices.

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