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Viet Nam-EU Health Cooperation: Fostering a Collaborative Partnership for Equitable Pharmaceutical Access

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Abstract

In the context of intensified Viet Nam-EU relations, health represents an area in which enhanced bilateral cooperation could be bolstered. Partnering towards equitable pharmaceutical access in particular is a domain with high potential for achieving shared gains. This paper calls for a collaborative partnership between institutions and pharmaceutical companies, with the aim of guaranteeing equitable access to pharmaceuticals to the Vietnamese people.

The paper presents in-depth research on the state of Vietnam's healthcare system, pharmaceutical industry and market, together with the role played by the EU and European pharmaceutical companies as Viet Nam's partners for healthcare strengthening and expanded pharmaceutical access. In light of this research, it provides recommendations to the Vietnamese Government, the EU, Vietnamese and European pharmaceutical companies active in Viet Nam to jointly attain sustainable solutions to strengthen the healthcare system, and to improve availability, affordability and quality of medicines in the country – three pillars considered essential to achieve equitable access to medical drugs.

Keywords: pharmaceutical cooperation, health cooperation, Viet Nam, EU, pharmaceutical companies, collaborative partnership, equitable access to medicines

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List of Abbreviations and Acronyms

AMR – Anti-Microbial Resistance

APIs – Active Pharmaceutical Ingredients

ASEAN – Association of South East Asian Nations

CPPs – Certificate of Pharmaceutical Products

CSR – Corporate Social Responsibility

DAH – Development Assistance for Health

DAV – Drug Administration Viet Nam

EC – European Commission

EMA – European Medicines Access

EPCs – European Pharmaceutical Companies

EU – European Union

FIEs – Foreign Invested Enterprises

FPA – Framework Participation Agreement

FTA – Free Trade Agreement

GDP – Good Distribution Practice

GIPAP – Glivec International PAP

GMP – Good Manufacturing Practice

GMs – General Managers

GPs – Good Practices

GPP – Good Pharmacy Practice

GSP – Good Storage Practice

ICH – International Council of Technical Requirements for Pharmaceuticals for Human Use

IPA – Investment Protection Agreement

IPRs – Intellectual Property Rights

LEMs – List of Essential Medicines

LMICS – Lower Middle-Income Countries

LoP – Law on Pharmacy

MOH- Ministry of Health

NCDS – Non-Communicable Diseases

NHI – National Health Insurance

OOP – out-of-pocket

SHI – Social Health Insurance

SMEs – Small and Medium Enterprises

PAPs – Patient Assistance Programmes

PCA – Partnership and Cooperation Agreement

PIC/S - Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme

R&D – Research and Development

ROs – Representative Offices

SDGs – Sustainable Development Goals

SHI – Social Health Insurance

TRIPS – Trade-Related Aspect of Intellectual Property Rights

UHC – Universal Health Coverage

WHO – World Health Organisation

WTO – World Trade Organisation

Executive Summary

Viet Nam and the European Union (EU) have been stepping up their bilateral relations in many areas. Health cooperation, and pharmaceutical cooperation in particular, represent an additional area in which enhanced bilateral cooperation could be achieved, so to obtain mutual benefits. Common objectives, interests and values make of Hanoi and Brussels natural partners in jointly working towards equitable pharmaceutical access in Viet Nam – a domain with high potential for achieving shared gains.

Following the Doi Moi reforms launched in 1986, Viet Nam's healthcare system underwent drastic transformations. It currently provides services through a mix of public and private providers and has achieved significant goals in Universal Health Coverage (UHC) thanks to the establishment of a government-reimbursed national scheme, the Social Health Insurance (SHI).

Despite health reforms and policies allowed for major accomplishments to be achieved, the sustainability and equity in health financing remains a challenge to address. Due to Viet Nam's changing economic status and disease burden, the current financing system on which the healthcare system is built may not be sustainable in the long term, holding a limited ability to face the new health challenges ahead. The capitation-based mechanism on which health financing is currently based reproduces historical inequalities in the allocation of financial resources for healthcare. Rethinking the way Viet Nam's healthcare system is financed would benefit the way care is provided to the population.

The pharmaceutical system was also transformed by the Doi Moi reforms, with the creation of new regulatory bodies and the introduction of new codes of conduct for the pharmaceutical industry. **Local manufacturing of pharmaceuticals has been growing steadily, and domestically produced medicines account today for a large part of the national market share**. The Vietnamese administration has supported and incentivised the domestic production of pharmaceuticals, and their local consumption. Domestic pharmaceutical production focuses on generics – and with higher production standards being introduced, Vietnamese generics are today not only responding to domestic needs, but also increasingly reaching advanced markets in Asia and Europe.

Despite these major accomplishments, to date the majority of innovative pharmaceutical products consumed in Viet Nam are of foreign origins. **Regulations surrounding manufacturing, import and distribution of pharmaceuticals by foreign companies remain complex**. Such complexity can at times prevent the availability and affordability of innovative treatments on the Vietnamese market. The Vietnamese administration has actively addressed these barriers. Despite many barriers being lifted and several regulatory advancements – such as the 2016 Law on Pharmacy (LoP), the signing of the

EU-Viet Nam Free Trade Agreement (FTA) and the creation of a National Pharmaceutical Database –, foreign pharmaceutical companies still face limitations in establishing and maintaining their operations in Viet Nam.

Viet Nam has obtained significant achievements in restructuring its healthcare sector, boosting its pharmaceutical industry so to make quality care and medicines more readily available. Nonetheless, a number of obstacles to equitable access to safe and high quality medicines remain – namely, (i) a widespread unfavourable perception of generics, (ii) a quality control mechanism with limited capabilities, (iii) a highly layered distribution system, (iv) a complex regulatory system and (v) a reimbursement system with limited flexibility.

Viet Nam's economy is growing, and the country will soon no longer be eligible as recipient of Development Assistance for Health (DAH) from the EU. Therefore, cooperation between Viet Nam and the EU in healthcare and pharmaceuticals should be prioritised and adapted to Viet Nam's changing economic status and needs. A pharmaceutical partnership is a promising option for continuing to jointly support Viet Nam's efforts to meet health demand with world-class quality services and products.

The EU has been an important partner for Viet Nam in pharmaceutical R&D and regulatory capacity building, supporting Viet Nam's efforts to improve equitable access to safe and high quality medicines in the country. The EU has been a pivotal partner in Vietnam's journey towards its alignment with international standards, supporting the country's integration within the global pharmaceutical market and jointly stimulating foreign investment. Despite challenges remaining in the effective implementation of some regulatory commitments**,** the signing of the EU-Viet Nam FTA and the Investment Protection Agreement (IPA), important building blocks of the EU-Viet Nam Partnership and Cooperation Agreement (PCA), will allow for an **easier flow of products, innovation and investments between the two parties, paving the way for a greater role for Viet Nam as pharmaceutical hub in ASEAN,** as well as **exporter of raw materials, semi-finished and finished pharmaceutical products**.

European pharmaceutical companies (EPCs) have been an important partner for Viet Nam in expanding access to medicines. For producers of patented drugs in particular, improving pharmaceutical access has acquired strategic significance. Companies have been formulating several access-related strategies – mainly in the form of access-oriented intellectual property management, product affordability and local capacity building – that allow for both short-term and long-term improvements in access to medicines. These access-related strategies are implemented by companies as they seek for reputational

and/or commercial payoffs, and need to be monitored to ensure that commitments effectively translate into compliance.

Please refer to the full list of recommendations formulated in view of this analysis.

EU-Viet Nam Cooperation in Health and Pharmaceuticals: Introduction

Viet Nam and the European Union (EU) have been stepping up their bilateral relations in many areas. From the signing of the Framework Participation Agreement (FPA) last autumn to that of the EU-Viet Nam FTA and IPA this February 2020, the two parties have shown their shared commitment in forging closer ties. Health cooperation represents an additional area in which enhanced bilateral cooperation could be achieved, so to obtain mutual benefits. **Partnering towards equitable pharmaceutical access in particular is a domain with high potential for achieving shared gains**.

The *health-in-all-policies* and *trade for all* approaches[1] witnessed throughout the policy dialogue that shaped the negotiations for the FTA represent a positive step in this direction. The process that has eventually brought to the signing of this agreement stimulated some positive changes in Viet Nam's pharmaceutical regulations. Furthermore, the agreement itself brings considerable benefits to the flow of pharmaceuticals between the EU and Viet Nam. It paves the way for the further strengthening of the role of the local pharmaceutical industry in the domestic and regional market, as well as in Europe. It also allows for international and European pharmaceutical companies in particular to expand their operations in the country. If well harnessed, these developments have a great deal of potential to bring about enormous benefits in terms of access to safe and high quality medicines for the Vietnamese population. Should Viet Nam succeed in turning the country into a new pharmaceutical hub, it would be beneficial for pharmaceutical access in other countries too.

Improving access to pharmaceuticals is a priority for both the Vietnamese government and the EU. Despite this shared objective, **Viet Nam and the EU have not yet formulated a clear and coordinated framework of action to jointly strengthen healthcare and enhance pharmaceutical access in Viet Nam**. A comprehensive strategic partnership for health and pharmaceutical development with the EU would support Viet Nam in achieving the country's objectives in these realms. Furthermore, expanding equitable access to medicines is becoming a strategic objective for EPCs – so to enhance their reputation as reliable global (and local) health actors and to boost commercial revenues through an expanded customers' target. Viet Nam could harness this growing interest in equitable access shown by EPCs, especially now that the EU-Viet Nam FTA will allow them to establish FIEs in the country. More cooperation between Viet Nam,

[1] The *health-in-all-policies* approach to policy making brings health considerations to the centre of policy discussions that are not directly concerned with the health sector. This approach stems from the acknowledgment that attaining positive and equitable health outcomes is not merely confined to healthcare. Social determinants of health can and must be addressed through intersectoral and multisectoral policy action. The health-in-all policy approach has become an integrant part of the EU's strategy to tackle health inequalities among its Member States and is gaining growing centrality in the EU's external action, especially in trade. For more information on the *trade for all* approach: https://trade.ec.europa.eu/doclib/docs/2015/october/tradoc_153846.pdf.

the EU, Vietnamese and European pharmaceutical companies would support, on the one hand, the growth of the domestic healthcare and pharmaceutical sectors and, on the other, the smooth and yet overseen mutual integration between Viet Nam and the global pharmaceutical market.

This paper calls for a greater role of health cooperation in Viet Nam-EU relations, arguing for a collaborative partnership between Vietnamese and European institutions and pharmaceutical industries. Aimed at strengthening the country's healthcare system and at guaranteeing equitable access to pharmaceuticals to the Vietnamese population, such cooperation should be built upon the comparative and complementary advantages that Vietnamese and European pharmaceutical companies hold in their respective portfolios. This paper carries out in-depth research on the state of Vietnam's healthcare system, pharmaceutical industry and market, together with assessing the role played by the EU and EPCs as Viet Nam's partners for healthcare strengthening, pharmaceutical development and expanded pharmaceutical access. In light of this research, the paper provides recommendations to the Vietnamese government, the EU, Vietnamese and European pharmaceutical companies and other stakeholders active in Viet Nam to jointly attain sustainable solutions to strengthen the healthcare system, and to improve availability, affordability and quality of medicines in the country – three pillars considered essential to achieve equitable access to medical drugs.

Europe and Viet Nam: Natural Partners

The Vietnamese government has shown its commitment to improving the country's economic performance and the livelihoods of its population. Despite significant goals having been achieved – for instance, in the realm of UHC and infectious diseases, as well as in boosting the production and consumption of locally-produced medicines –, the healthcare and pharmaceutical sectors yet remain domains with room for considerable improvements.

Policy actions undertaken by the Vietnamese administration throughout the last decade in particular have shown that Viet Nam fully acknowledges the health-economy nexus. Working towards a sustainable and resilient healthcare system where the quality, availability and affordability of pharmaceuticals is enhanced is beneficial to people's health and, consequently, the country's economy. Improving health-related outcomes has had a positive impact on poverty alleviation and on living standards, further tackling inequalities, and preventing unnecessary deaths. The Vietnamese government has also demonstrated to be aware and prone to action on the challenges ahead. Given

Viet Nam's aging population[2] and increasing burden of non-communicable diseases (NCDs), a more equitable access to – and rational use of – pharmaceuticals is bound to translate into greater long-term benefits, such as a lowered mortality due to preventable and treatable NCDs. Finally, a further enhancement of the regulations surrounding pharmaceutical imports, manufacturing, quality and distribution would support fair competition within the country, potentially making Viet Nam a pharmaceutical hub in the Association of South East Asian Nations (ASEAN) region and vis-à-vis the European and global market.

Viet Nam could once again find in the EU a partner that is particularly well-positioned to support its efforts in strengthening the healthcare system and fostering equity and quality in pharmaceutical access in the country. Not only are both parties committed to achieve the health-related goals included in the Sustainable Development Goals (SDGs), they also share a long-lasting history of successful health cooperation in realms such as UHC, anti-microbial resistance (AMR) and infectious diseases. In view of the mounting geopolitical and global challenges faced by the European side, the EU is likely to be willing to play even a greater role in support of health globally. In this context, becoming Viet Nam's partner in healthcare strengthening and pharmaceutical development would be a compelling area to start a new page for the EU's global health engagement.

Building upon the central tenets of partnership among equals and collaboration between institutions and companies, **this partnership could also potentially pave the way**, in the near future**, for a greater role for Viet Nam in responding to the EU's pharmaceutical needs**. The Vietnamese pharmaceutical industry is growing and integrating in the international market at a steady pace, boasting today higher manufacturing and production standards than ever before. The determination of the Vietnamese administration to strengthen the local pharmaceutical industry comes at a time when the EU, its Member States and EPCs are urgently looking to diversify their import origins – in terms of generic medicines and semi-finished pharmaceuticals products, as well as Active Pharmaceutical Ingredients (APIs) and other pharmaco-chemical raw materials. Forging closer ties with the EU and EPCs to support and accelerate the strengthening of Viet Nam's healthcare and pharmaceutical sectors could also be pivotal in accelerating the rise of Viet Nam as an exporter in the global pharmaceutical industry.

The presence of a substantial number of EPCs active in Viet Nam represents a potential asset in view of an EU-Viet Nam collaboration aimed at expanding pharmaceutical access in the country. Together with local companies and stakeholders from the healthcare and

[2] According to data gathered by the World Bank, Viet Nam's population above 65 years old went up from roughly 1million and a half in 1960 to almost 7million in 2018, representing 4.7% and 7.3% of the total population respectively. With the median age growing from 21.1 in 1990 to 32.5 in 2020, Viet Nam's ageing population is expected to growth sensibly over the coming decade.

pharmaceutical sector, these companies could become a complementary but yet central set of players. EPCs have shown a growing interest in contributing to a more equitable pharmaceutical environment, gradually modifying their business approach in lower middle-income countries (LMICs) like Viet Nam and stepping up their role as respondents to calls for global health action. The most evident facets of this new business approach lie in the progressive adoption of more inclusive business models geared towards reaching low-income groups, and in the growing inclusion of goals related to access to medicines[3] – not just as part of their Corporate Social Responsibility (CSR) strategies, but also as central tenets of companies' business strategies. This change of course stems from the soaring demand for pharmaceuticals in the world's emerging economies, with developing countries accounting for a constantly growing share of the global pharmaceutical spending (AMF,2019).

Viet Nam holds a number of features that make the country particularly appealing for international and European pharmaceutical companies willing to broaden their market outreach by improving access to medicines. The country has a significant burden of infectious diseases and a growing rate of NCDs, UHC coverage rates and Out-of-Pocket (OOP) expenditures for medicines are both high, and health expenditures are increasing by 12% per year (PMB, 2019). Despite the growing involvement of pharmaceutical companies, the strategies that have been adopted to improve access to pharmaceuticals in Viet Nam, on the one hand, face a number of limitations due to the local regulatory environment and, on the other, lack of coordination, specificity and measurability in their efforts. A coordinated strategy developed in collaboration with Vietnamese institutions, with the support of their European counterparts, is needed to address these limitations, fully unleashing the power held by the private sector in contributing to equitable access to medicines.

These considerations underpin the **view of Viet Nam and Europe as natural partners** in supporting further health and pharmaceutical development in the country, in view of shared priorities and objectives. Focusing on the actions undertaken by the Vietnamese administration, the EU, Vietnamese and European pharmaceutical companies to improve healthcare's efficiency and access to medicines, this paper discusses what has so far been achieved and provides recommendations on how to move forward – towards a Viet Nam-EU collaborative partnership for equitable pharmaceutical access and healthcare strengthening in Vietnam. The following chapter introduces Viet Nam's healthcare sector, pharmaceutical industry and market, discussing achievements and further aspects to be

[3] For an analysis of business ethics in the pharmaceutical industry see, among others, Fürst, M. (2019), "Reframing the Pharmaceutical Sector Contribution to Access to Medicines and Universal Health Coverage: A Business Ethics Perspective", in Sturchio, J.L. et al. (2019), *The Road to Universal Health Coverage: Innovation, Equity, and the New Health Economy*, John Hopkins University Press, pp. 143-173.

addressed in these deeply interconnected realms. The second chapter critically engages with the role played by the EU and EPCs in supporting equitable access to high-quality pharmaceuticals in Viet Nam. Lastly, the conclusive chapter provides recommendations to Vietnamese and European policy makers, as well as to Vietnamese and European pharmaceutical companies, as in how to effectively work together in order to strengthen Viet Nam's healthcare system and ensure that both generics and innovative medicines are available and affordable to patients.

1. Being Healthy in Viet Nam: Healthcare and Pharmaceutical Systems

This chapter provides an overview of major achievements and remaining issues in the management of Viet Nam's healthcare and pharmaceutical systems. It specifically looks at how the organisation of these systems impacts equitable access to care and to safe and high quality pharmaceuticals. The discussion attempts to provide a comprehensive and balanced picture, encompassing domestic and external considerations, interests and developments.

1.1 Main features of Viet Nam's Healthcare System

Viet Nam's healthcare system was reformed along with the economy, moving from a classical socialist model to what has been defined as a socialist-oriented market model. Following the economic reform process initiated in 1986, known as 'Doi Moi', the country's socialist-style healthcare system was liberalised, and user fees were introduced (Somanathan et al., 2013). **Economic and healthcare system reforms have had a positive impact on both the country's economic development and health-related outcomes.** Since the 1980s, while the economy has grown steadily, life expectancy has been increasing and infant mortality rates declined (Kien et al., 2014). Throughout the last two decades in particular, a steady growth in both total and per capita health expenditure has been witnessed (Nguyen et al., 2017; Teo et al., 2019).

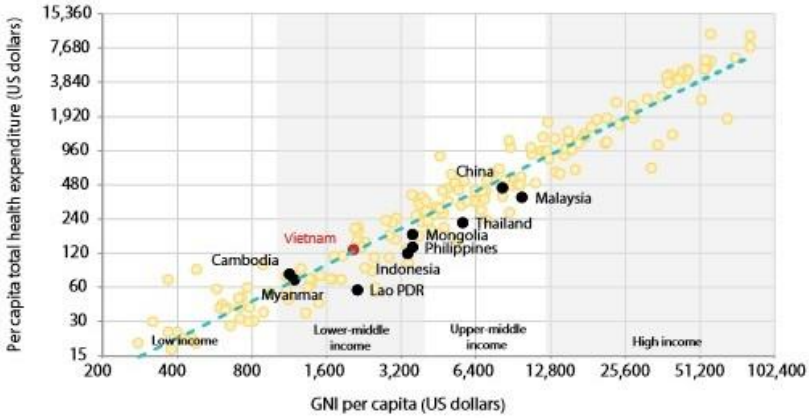


Figure 1.

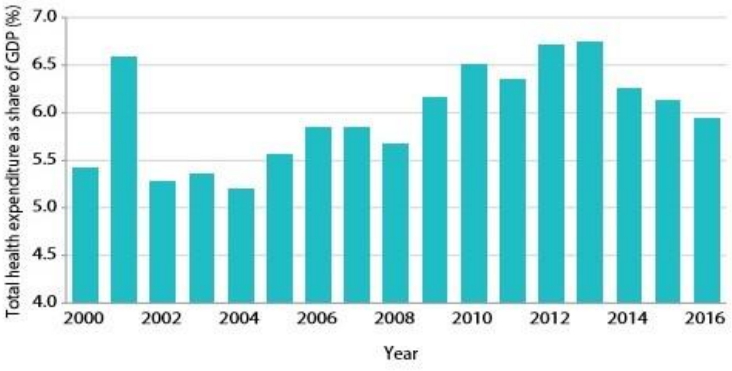
Total Health Spending, Vietnam versus Comparator Countries, 2016.

Source: Teo et al., 2019.

Figure 2.

Vietnam Total Health Spending as a Share of GDP, 2000-2016.

Source: Teo et al., 2019.



Today, healthcare in Viet Nam is provided to the population by a mix of public and private entities, with the services of the latter becoming increasingly central to the national health system. Overall, four different administrative levels of healthcare facilities can be found:

- level I, comprising central and city hospitals.
- level II or provincial facilities, serving for a population of around 1-2 million people in provinces.
- level III or district healthcare facilities, covering a population between 100.000 and 200.000 in districts.
- level IV or communal hospitals, for a population of 5000-10,000 in communes.

Public central hospitals are owned by the Ministry of Health (MOH), whereas city hospitals by bigger municipalities. The other levels of public healthcare facilities are owned by provincial governments. Private providers are also found at all four levels, although differences between public and private healthcare entities are still evident. Hospitals are predominantly public: the public healthcare system is organised so that most services are provided through level I facilities, which results in hospitals' overcrowding. Lower level public facilities are generally less developed, with severe consequences for the ability of the public sector to provide effective primary care outside hospitals. In the private sector, level I facilities are smaller and fewer than their public counterparts; private providers are more primary care oriented, focusing on small ambulatories and outpatient care. (Somanathan et al., 2013; Nguyen et al., 2017; Takashima et al., 2017)

Viet Nam has reached considerable achievements in the realm of UHC. Since the 1990s, the Vietnamese government has put in place policies aimed at reducing health-related OOP expenditures. These policies wanted to counter the higher financial burden put on care seekers since health sector reforms were set into motion and user fees were introduced. Health reforms in fact greatly affected the possibility of accessing health services for the poorest parts of the population. In 1993, a mandatory scheme was introduced covering the health expenditures for civil servants, formal sector workers and people receiving social assistance. Initially administered at a provincial level, by the end of the 1990s the provincial schemes were unified and evolved into a national health insurance (NHI) fund. As for the poorest parts of the population, since the 1990s the Vietnamese government has attempted to develop health insurance mechanisms to provide coverage for the less wealthy.

The policies formulated were difficult to implement, as decrees aimed at guaranteeing fee exemptions were not coupled with governmental financing to health facilities. In 2005 the exemption policy was eventually abandoned, and the government started financing the premiums for a health insurance scheme, to which all the underprivileged had to be

enrolled. This development was followed, in 2009, by the promulgation of the Law on Health Insurance, according to which the government is responsible for the payment of health insurance premiums for meritorious individuals and protected groups – namely children under six, the elderly, the poor and the near-poor, for which enrolment to this SHI scheme is mandatory.[4] **The reimbursement system in place prioritises care obtained through public hospitals** (level I), **further exacerbating hospitals' overcrowding and underdevelopment in public facilities at the district and commune level** (level III-IV) (Matshushima et al., 2013; Somanthan et al., 2013; Takashima et al., 2017)

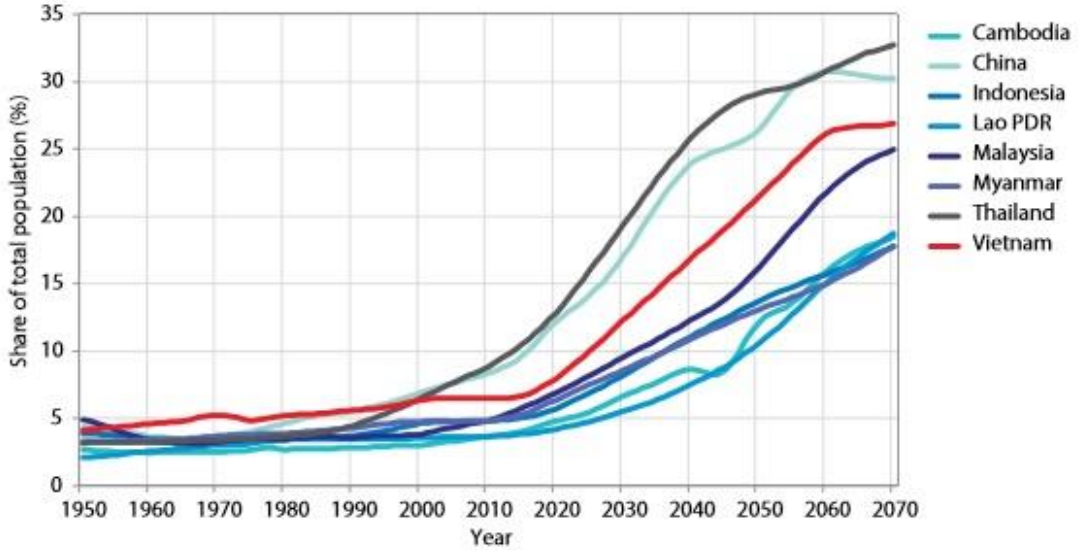


Figure 3. Share of Population Age 65 or Older, Vietnam versus Comparator Countries, 1950–2070. Source: Teo et al., 2019.

1.2 Healthcare System Financing: Between New and Old Challenges

Economic development, together with the health reforms and policies discussed above, have positively influenced the country's overall health development and health-related outcomes. Nonetheless, two main structural obstacles remain that are connected to the

[4] According to the General Statistics Office of Viet Nam (GSOVN), the Government's poverty line for the 2011-2015 period was calculated by monthly average income per capita of households. The 2016-2020 poverty line published by the Government started using a multidimensional poverty approach (Decision No.59/2015/QD-TTg) combining income poverty measurement and a multidimensional poverty measure based on the Alkire-Foster method. Poverty indicators for the 2016-2020 are as follows: poor households in rural areas have a monthly per capita income of VND 700,000 or lower, or have a monthly per capita income of between over VND 700,000 and VND 1.000. 000 and are deprived of at least 3 indicators measuring deprivation of access to basic social services. In urban areas, poor households have a monthly per capita income of VND 900,000 or lower, or have a monthly per capita income of between over VND 900,000 and VND 1.300.000 and are deprived of at least 3 indicators measuring deprivation of access to basic social services. Near-poor households in rural areas have a monthly per capita income of between over VND 700.000 and VND 1,000,000 and are deprived of less than 3 indicators measuring deprivation of access to basic social services; in urban areas, have a monthly per capita income of between over VND 900.000 and VND 1,300,000 and are deprived of less than 3 indicators measuring deprivation of access to basic social services. For Multidimensional poverty in Viet Nam see, among others, Lo Thi Duc (2019), "Multidimensional Poverty in Viet Nam: Sustainable Poverty Reduction 2016–2020", in Dimensions, Multidimensional Poverty Peer Network, 2019:8, pp. 4-9.

way healthcare is financed. These obstacles need to be addressed, as they hinder the effectiveness of Vietnam's healthcare system.

The first set of issues relates to the **sustainability of the healthcare system's financing** vis-à-vis a growing number of health-related challenges. Sustained policy efforts and a steady growth in public spending on health have resulted in substantial health-related achievements and health insurance coverage over the last two decades. Nonetheless, OOP expenditures for health remain the predominant source of health system financing in Viet Nam. In the near future, the Vietnamese health system is bound to face new health challenges connected to economic growth, rising living standards and a fast ageing population – and to the consequent shift in the country's disease burden.

Rank in 2017		Category	Percentage			
			1990	2000	2010	2017
1	Cardiovascular diseases	NCD	11.7	14.5	15.9	17.0
2	Neoplasms	NCD	6.9	9.4	11.2	13.1
3	Musculoskeletal disorders	NCD	3.6	5.1	6.3	6.9
4	Diabetes and kidney diseases	NCD	3.3	4.3	5.1	6.2
5	Neurological disorders	NCD	3.5	4.7	5.3	5.4
6	Other NCDs	NCD	7.8	6.7	5.9	5.0
7	Unintentional injuries	INJ	6.7	6.3	5.6	5.0
8	Mental disorders	NCD	3.4	4.5	4.9	4.9
9	Transport injuries	INJ	4.2	4.8	5.6	4.9
10	Respiratory infections and tuberculosis (TB)	CD	11.1	7.1	5.5	4.4
	DALYs per 100,000 population		33,766	26,510	25,785	25,809

Figure 4. Top Ten Causes of Disease Burden, 1990–2017. Source: Teo et al., 2019.

The question lies in the readiness and ability of the public healthcare system to provide effective, high-quality care for the growing population of one of the fastest-ageing countries in Asia – and to do so without putting further financial burden on households. From a financing perspective, the public funding for health in place is built on state budget and SHI revenues. This financing model, that focuses heavily on hospital-level care, is not sustainable nor able to guarantee quality care in the long run. Viet Nam's fast ageing population and growing middle class are putting new pressure on the healthcare system, while public fiscal resources for health are shrinking. The country's wide-reaching SHI, a government-reimbursed premium system that aims to cover the essential healthcare needs of the entire population through the public healthcare sector, is not sustainable in face of growing challenges and health needs of the population. Viet Nam's burden of NCDs is increasing, and conditions such as diabetes, cardiovascular diseases and cancers will require additional policy efforts, research initiatives and funding to ensure that effective prevention, diagnosis, and treatments for these conditions are

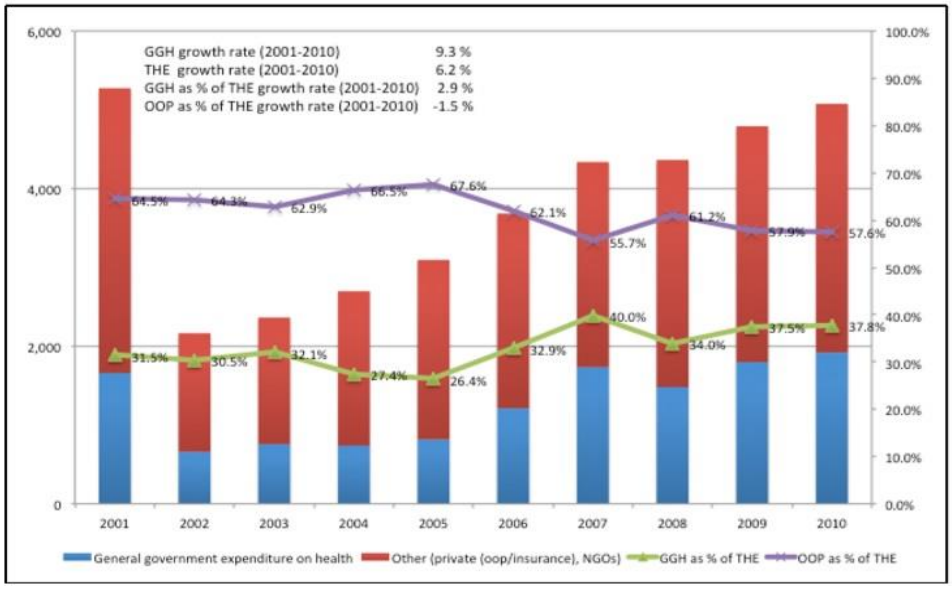
systematically available to the entire population. Although the Vietnamese government formulated a national strategy on NCDs, this strategy has been difficult to implement and has brought to light some important structural challenges within the healthcare system. Among these, the most evident are a limited experience and access to knowledge on NCDs among health personnel, with the local healthcare infrastructure and workforce still having a long way to go before being fully prepared to effectively tackle these conditions, in care levels below hospitals. (Kien, 2014; Teo et al., 2019)

Figure 5..

Health Expenditure Trends and Composition, 2001–10.

Source: Teo et al., 2019.

Note: GGH = Government General Health expenditures. OOP = out-of-pocket payments. THE = Total Health Expenditures.



The injection of substantial financial resources would ensure that services, competencies, and quality of care in the healthcare system are adequate to meet these new needs – not just at hospital level but also and more importantly at primary care level. Nevertheless, **public health expenditures alone risk not to be able to meet these needs, especially now that Viet Nam's fiscal consolidation leaves little space to increased public expenditure in the health sector**. In addition, the need for greater public expenditure focusing on NCDs comes at a time when Viet Nam's economic growth has impacted the country's eligibility as aid receiver, with a progressive decline in development assistance for health received by international donors. This development implies that key health programmes for communicable diseases and immunisation should be progressively taken over and managed through domestic funding, a factor that will put the system under further stress (Teo et al.,2019). The Vietnamese administration has shown its determination to act upon this changing reality: for instance, already in 2014, the Vietnamese government set targets aimed at encouraging the local production of the majority of the vaccines for domestic consumption (Decision No. 68/QD-TTg, 2014).

The second set of challenges concerns **equity in health financing**. The disproportionate allocation of funding and resources causes inequalities in access to healthcare, both among different groups within cities as well as between rural-urban populations. In Viet Nam's case, this has considerable implications for the extent to which UHC indicators effectively translate into improved access to quality healthcare for the poor and more vulnerable parts of the population. The financing mechanism in place to support the policies connected to the 2009 Law on Health Insurance is based on a capitation-based system which, in practice, reproduces patterns of inequalities in healthcare access between underprivileged and wealthy people – and provinces – in Viet Nam. This financing system allocates funds according to historic expenditures and utilisation patterns of the groups enrolled for health insurance at a commune or district-level facility within a given geographical area. But financial, geographical and social barriers have historically led the less wealthy to utilise and spend less on healthcare.

As a result, this financing mechanism allocates more capital to facilities and practitioners dealing with well-off patients, who tend toward higher health-related expenditures. Therefore, **this capitation-based system exacerbates the gap in quality of care and technology available to facilities catering for poorer segments of society**. It also leads facilities and practitioners to limit the provision of health services for the poor and vulnerable, given the lower value of the capitation rate received from the government to care for those groups. Despite virtually the vast majority of underprivileged groups among the Vietnamese population are enrolled in a national health insurance scheme, in practice their access to quality healthcare still faces significant structural limitations, that need to be addressed with urgency (Somanathan et al., 2013).

Rethinking the way Viet Nam's healthcare system is financed would undoubtedly benefit the way care is provided to the population. New financing mechanisms could be enabled to sustain the additional expenditures required by the country's long-standing and more recent health needs. In particular, Viet Nam could create new resources to allow for healthcare reforms in support of primary care development.

1.3 Evolution in Viet Nam's Pharmaceutical System: A Critical Overview

As a result of the Doi Moi reforms, Viet Nam's pharmaceutical system underwent dramatic transformations. The pharmaceutical supply chain went from being centrally controlled to be subjected to market forces, and liberal regulations in the realm of pharmaceutical trade, manufacture, distribution and sale were progressively introduced. Consequently, the Vietnamese pharmaceutical market grew rapidly while gradually opening to foreign pharmaceutical products and investors. Domestically, private pharmacies also mushroomed and, along with them, OOP expenditures for medicines soared. (Witter, 1996; Nguyen et al., 2015).

To follow up on this liberalisation, the Government of Viet Nam engaged in the **building of a more effective pharmaceutical regulatory environment**, establishing administrative entities dedicated to the issuing of pharmaceutical policies. Established in 1996, the Drug Administration of Viet Nam (DAV) has been commissioned with tasks such as product registration and the development of good practice roadmaps, aimed at monitoring quality assurance and quality control of medicines along the supply chain. Good Manufacturing Practice (GMP), Good Storage Practice (GSP), Good Distribution Practice (GDP) and Good Pharmacy Practice (GPP) are the main codes of conduct to be followed by manufacturers, importers, distributors and retailers respectively so as to ensure that the medicines circulating in the market respect good standards of quality (Nguyen et al.,2015; Angelino et al., 2017).

Local manufacturing of pharmaceuticals has been growing steadily and diversifying, with domestically produced medicines accounting today for a large part of the national market share. The Vietnamese government is in fact successfully supporting the **transition from a heavily import-reliant pharmaceutical market to one that is largely based on locally manufactured products**. Since 2005, with the Law on Pharmacy No. 34/2005/QH11, the Vietnamese government has growingly encouraged, where possible, the substitution of brand-name pharmaceuticals with their domestically produced bio-equivalents (Nguyen et al., 2017). Building on this initial step, in January 2014 the Prime Minister Decision No. 68/QD-TTg officially launched the National Strategy on Viet Nam pharmaceutical industry's development to 2020, and with a vision to 2030.[5] The Strategy represents a fundamental linchpin for Viet Nam's pharmaceutical industry, that sets significant developmental objectives. It aims at further supporting the building of a national pharmaceutical industry that focuses both on safe quality generic drugs, and specialised and modern products. The Strategy also set targets to scale up the local production of pharmaco-chemical raw materials and the manufacturing of vaccines for domestic consumption. By doing so, the objective is twofold: to gradually replace imported medicines and make Vietnamese pharmaceutical products more compatible not just nationally, but also on the regional and global pharmaceutical market. This strategy is particularly relevant to access to medicines, as it shows the commitment of the Vietnamese government to better ensure that domestically produced pharmaceuticals are of safe quality, rationally priced, and used in an adequate and effective manner.

The impact of these policies can be already felt. Although limited funding and Research & Development (R&D) capabilities result in Vietnamese drug firms mainly producing generic medicines, these products are growingly used by domestic consumers. The number of

[5] For more information about the National Strategy, see: https://vanbanphapluat.co/decision-no-68-qd-ttg-the-national-strategy-on-development-of-the-vietnam-pharmaceutical-industry-up-to-2020.

pharmaceutical products produced in Viet Nam is growing steadily, thanks to frequent updates of the list of medicines including documents proving biological equivalence (see, among others, 207/QD-BYT, 2020). Higher standards in the domestic pharmaceutical industry are progressively being adopted, a growing number of investments are targeting the development of research facilities and the training of local talents, and national campaigns are being launched to raise public awareness and encourage the prescription and use of safe quality drugs produced in Viet Nam.

As a result of these developments, Vietnamese generics have been increasingly reaching more advanced markets both in Asia and Europe, such as Japan, China, Germany and France, among others. This development stands in contrast with previous export trends: throughout the first decade of the 2000s in particular, the vast majority of drugs produced in Viet Nam tended to be sold to less competitive markets, where pharmaceutical standards are lower and regulatory policies less developed – mainly to Laos, Myanmar and Cambodia, as well as to several African states, primarily to Nigeria.[6] In the upcoming years, **national and foreign investments in R&D and local production of APIs are expected to continue growing and to have a positive impact on the Vietnamese pharmaceutical industry and market.**

Despite these major accomplishments, to date the majority of innovative pharmaceutical products consumed in Viet Nam remain of foreign origins. Overall, a significant share of innovative pharmaceutical products circulating on the Vietnamese market reaches the countries through foreign companies and foreign-local joint ventures, either through import – of pharmaceutical end products, APIs and other raw materials – or through FIEs increasingly engaging with local pharmaceutical production (Angelino et al., 2017; Nguyen et al., 2017; Harris, 2018). In the coming years, the above-mentioned policies in support of a strengthened domestic pharmaceutical industry are expected to change this course, with local companies playing a greater role in the production of innovative drugs.

[6] Considerations of the author stemming from export data on packaged medicaments retrieved from the OEC website.

Local manufacturers, together with the sporadic FIEs holding distribution rights involved in production ventures jointly developed with local companies, can sell their products directly on the Vietnamese market both through public and private retailers. Foreign pharmaceutical companies with representative offices (ROs) in Viet Nam and FIEs with import rights, on the other end, can only introduce and register their drugs in the country, to then develop relationships with local wholesalers and distributors that will bring their products to the market. Importers, distributors and retailers are free to set their prices within comparative bands that are subsequently stabilised by the government (Nguyen et al., 2017; VILAF, 2017).

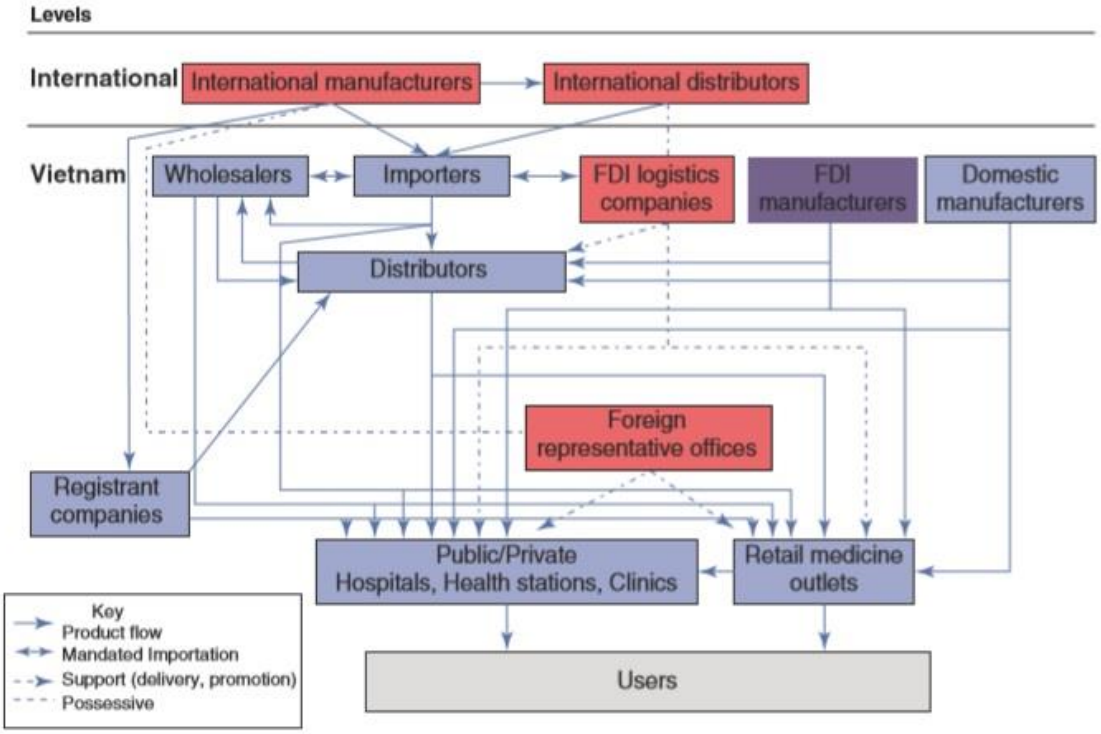


Figure 6. Pharmaceutical Supply Chain in Viet Nam. Source: Nguyen et al., 2017.

Today, Viet Nam's pharmaceutical market is growing as fast as its economy. A larger, wealthier, and fast-ageing population with overall higher living standards has stimulated a rapid and steady surge in the country's pharmaceutical demand and drug spending per capita over the last decade (Angelino et al., 2017). With the vast majority of the population covered by UHC, a growing number of pharmaceutical products included in the List of Essential Medicines (LEMs) is being purchased through hospital pharmacies and reimbursed through government subsides. Currently, domestic and imported products compete for public procurement almost on a level playing field. The growing competitiveness of locally produced pharmaceuticals, together with the increasing familiarisation of the local population with these products, is expected to counterbalance the progressive opening of public procurement to EPCs included in the EU-Viet Nam FTA.

Nonetheless, **the way pharmaceutical public procurement and reimbursement system are organised carries several limitations** that challenge the swift availability and affordability of safe and high-quality treatment. First, **the LEMs is published unfrequently**. As a result, innovative treatments usually take longer to reach the public market and to become available for reimbursement than they would if such list was more readily available and systematically updated at set timings. Second, **reimbursement through the SHI is organised in such a manner that pharmaceutical expenditures are only reimbursable when patients get referred to a hospital and obtain a prescription from there**. This not only puts further pressure on hospital-level care, but also disincentives the use of SHI by those living far from hospitals and/or seeking fast prescription for known conditions. To shorten the process, a significant number of pharmaceutical purchases takes place through private pharmacies – which are consequently expanding their footprint in the Vietnamese pharmaceutical market.[7]

The regulations surrounding market access and distribution of foreign pharmaceutical products in Viet Nam are known for being particularly complex. In order to address the main barriers hindering the establishment of a faster mechanism for pharmaceutical development, import and marketing, the Government of Viet Nam has engaged in significant **restructuring of the legal framework regulating pharmacy practice, pharmaceutical development and business** throughout the last decade. A milestone in this regard is the Law on Pharmacy, promulgated in 2016 and taking effect in January 2017 (hereby referred to as the '2016 LoP', 'LoP' or 'Pharma Law').[8] This new law established regulatory improvements in support of the expansion of local manufactures while simultaneously lifting barriers to new foreign products, so as to increase fair competition. According to this law, locally manufactured drugs that comply with pharmaceutical standards are prioritised over imported products during public procurement. Significantly, the LoP removed the 5-year rule for clinical trials, accelerating the availability and affordability of new drugs to Vietnamese consumers, while freeing foreign companies from additional financial burdens when introducing a new treatment in Viet Nam. The 2016 LoP also recognised the specialty of Clinical Pharmacology, and permitted parallel imports provided that the price of the imported product is lower than the original brand-name drug sold in Viet Nam. In line with Viet Nam's alignment to WTO commitments, the law also establishes a legal framework for foreign pharmaceutical

[7] Considerations of the author arising from the insights gained during the interviews with Mathieu Fitoussi, General Manager (GM) of Servier Viet Nam, and with Dan Millard, GM of GlaxoSmithKline (GSK) Viet Nam. With headquarters in France and the UK respectively, Servier and GSK have been active in Viet Nam since the 1990s. Servier Viet Nam focuses on brand-name treatments for NCDs, with a strong portfolio in hypertension and other products for diabetes, chronic cardiovascular and coronary diseases. GSK's pharmaceutical portfolio focuses on antibiotics, anti-infective respiratory products, as well as on treatment for urologic conditions.
[8] The full text of the Law is available here:
https://vss.gov.vn:3535/File_Server_BHXH/documents/Law10516.pdf.

companies willing to set up FIEs with import and/or trading distribution rights in Viet Nam (VLLF 2016, VILAF 2017).

Viet Nam has been active in building a strong, cutting-edge pharmaceutical management system, working towards the establishment of an **integrated online mechanism that brings together all the relevant stakeholders in the pharmaceutical industry** – from the Ministry of Health to pharmaceutical manufacturers, wholesalers and retailers. The Decision 412/QD-BYT outlines the regulations and responsibilities held by each and every stakeholder along the pharmaceutical supply chain in the creation of a National Pharmaceutical Database System. This ambitious system aims at reducing paper reports for those pharmaceutical facilities and businesses adhering to Good Practices (GPs, namely GMP, GSP, GDP and GPP). This database not only shows Viet Nam's full commitment to follow international pharmaceutical standards, but also has the potential to ease the flow of data, allowing for improved data exchange within pharmaceutical stakeholders in the country. Following pharmaceuticals from production to marketing would also strengthen Viet Nam's ability to fight counterfeit drugs and to implement effective quality control mechanisms.

1.4 Remaining Obstacles to Access to Safe and High Quality Medicines: Regulatory, Structural and Behavioural Issues in Context

The previous sections discussed the significant achievements obtained by the Vietnamese government in restructuring its healthcare sector, boosting its pharmaceutical industry and market so to make quality healthcare and medicines more readily available to the Vietnamese population. Despite major objectives having been reached, **a number of obstacles to equitable access to safe and high quality medicines remain**, that need to be addressed to fully meet the health needs of the population – as well as to unleash the high potential of the Vietnamese pharmaceutical industry.

To better understand the issues underpinning the remaining barriers in access to safe and high quality medicines in Vietnam, it is important to focus on four aspects – namely, (i) the perception of generic medicines and the consequent prescription, purchasing and consumption behaviour of the population, (ii) a quality control mechanism with limited capabilities, (iii) a highly layered distribution system, (iv) a complex regulatory system and (v) the reimbursement system in place.

The first aspect that hinders equitable access to medicines is connected to the perception of generic medicines held by healthcare professionals, pharmacists and the population in Viet Nam. Studies have proven that, despite the efforts of the Vietnamese government to incentivise the public procurement, prescription and use of bioequivalent products, **a large share of pharmacists in Viet Nam hold limited knowledge of generic products and**

remain rather sceptical about therapeutic equivalence of generic products. This is particularly true among those pharmacists who received limited training (Tran et al., 2018). Turning to the Vietnamese people's drug-related behaviour, a vast part of the population self-medicate, with private pharmacies often being the first – if not the only – health service they come in contact with. Education about the importance of rational use of medicines and treatment adherence is low, and illicit drug-selling practices are recurrent. This leads to several problems. First and foremost, it is one of the factors underpinning the persistence of high OOP expenditures for health, as many pharmaceutical products are purchased outside of the reimbursement schemes in place with the SHI. As for communicable and infectious diseases, one of the leading causes of high AMR in Vietnam lies in the irrational use of medicines, together with the possibility of purchasing 'prescription-only' medicines without any prescription. This behaviour has important implications for the perception and use of generics:

> Lack of knowledge of generic medicines and misconceptions that a cheaper price equates to poorer quality also contributed to low acceptance of generics [among the Vietnamese population]. Vietnam did not have any financial incentives to promote prescribing of generic medicines, whereas promotional incentives from [foreign] pharmaceutical industries for prescribers to recommend more expensive branded products are prevalent (Nguyen et al., 2017).

The formulation of **a clear and comprehensive generics strategy** by the Vietnamese administration, to complement the existing efforts in boosting generics consumption and production, could help overcoming these remaining issues.

A second obstacle to equitable access to high-quality pharmaceutical products in Viet Nam is related to the **mechanisms intended to ensure pharmaceutical quality** – especially for generics that are locally produced or imported from other countries, notably Asian ones. Viet Nam has been scaling up the existing quality assurance and control mechanisms, frequently withdrawing products from the market that failed to keep up with quality standards, as well as increasing controls on domestic production facilities. Nevertheless, problems of enforcement due to a restricted number of pharmaceutical inspectors and testing capacity in the country remain in place. This limited human and infrastructural capacity often results in suboptimal inspections of manufacturers and distributors (Nguyen et al., 2017). Consequently, pharmaceutical quality in Viet Nam may not always be optimally guaranteed, especially for generics imported from countries like India and China struggling to ensure quality to be strictly maintained along the supply chain.[9] Counterfeit brand-name drugs represent another pressing issue in terms of access to quality medicines for the population. Counterfeit drugs can at times be found on the shelves of private pharmacies, often selling prescription-only drugs to patients that are not in possession of

[9] From the interview with Mathieu Fitoussi, GM Servier VN.

any prescription. The implementation of the above-mentioned **National Pharmaceutical Database System (412/QD-BYT, 2020) will surely support quality control and assurance in the country.** During the current Covid-19 crisis, the Vietnamese administration has demonstrated to be fully aware of the threat of counterfeit and sub-standard quality drugs circulating the domestic market, especially following the disruption to the pharmaceutical supply chain resulting from the pandemic. In 3838/QLD-CL (14/04/2020), the DAV vocally recommended health departments, pharmaceutical producers, importers, wholesaler and retailers to step up their quality inspection at each step of the supply chain. All relevant stakeholders should act jointly to ensure quality standards are respected, and counterfeit products are rooted out of the market.

Viet Nam's **medicine supply system** – a highly layered and complex pharmaceutical distribution system also described in the previous section – represents a third impediment to equitable pharmaceutical access in the country, carrying important consequences for both affordability and availability of medicines. The comparative pricing bands within which prices are set are framed in a complex and vague way that allows companies, wholesalers and retailers to make use of loopholes to sell medicines at inflated prices. Even when companies do have differential pricing strategies in place for specific products, and although they can and often do suggest prices to distributors**, 'there is a limited framework in place to ensure that these prices reach the patient at the end of the chain'**.[10] Consequently, some pharmaceuticals in Viet Nam tend to be sold at higher prices compared to other countries in the region with similar – or even higher – overall purchasing ability among the population (Angelino et al., 2017; Nguyen et al. 2017). The local administration, together with public and private stakeholders could develop comprehensive and transparent pricing procedures and standards to incentivise fair pricing.

The fourth aspect that poses barriers to equitable access to pharmaceuticals in Viet Nam refers to the country's **complex regulatory system for the approval and marketing of foreign pharmaceuticals**, which can challenge the swift and continuous availability of innovative treatment. It has been mentioned above how Viet Nam has engaged with a restructuring of its regulatory framework surrounding pharmaceuticals, with the 2016 LoP removing the obligation of clinical trial for new drugs. This development resulted in significant improvements in the registration process, limiting additional expenditures for companies and shortening the time necessary for a new pharmaceutical product to reach the Vietnamese market.

Although many achievements have been obtained in this regard, regulations concerning the pharmaceutical system remain difficult to navigate, especially for foreign companies.

[10] Quote from the interview with Dan Millard, GM GSK VN.

Overall, companies' representatives interviewed for this paper showed dissatisfaction towards the persistence of overlapping regulations, administrative encumbers and barriers, together with limited clarity and frequent regulatory changes. **From the perspective of the European pharmaceutical industry, pharma-related decrees and circulars are often entering into force without sufficient consultations**, which leads to regulations that tend to be overly prescriptive, including many grey areas.

In particular, there exist administrative barriers, as a result of the Vietnamese Ministry of Health **Circular No. 32/2018/TT-BYT**, [11] addressing regulations involving the registration of drugs and drug materials, issued in 2018. It arose as a particularly pressing issue, posing administrative impediments to the industry and, consequently, hindering pharmaceutical availability for the Vietnamese population. Through this circular, effective since September 2019, the DAV is not only requesting the renewal of the market authorisation for pharmaceuticals every five years, but it is also asking for special documentation that goes beyond international standards - introducing requirements for the renewal of the Certificate of Pharmaceutical Products (CPPs) that are exclusive to Viet Nam, over and above WHO standards and often not workable in most regulatory authorities around the world. As a result, pharmaceutical products of foreign origins sometimes struggle to be introduced or re-approved for marketing in Viet Nam, with negative impacts on patients' access to pharmaceutical products. **Addressing these administrative challenges would guarantee innovative drugs to become readily available on the Vietnamese market**.

A fifth obstacle to equitable access to medicines is connected to the way the country's pharmaceutical **reimbursement system** is organised. As mentioned in the previous section (p.17), the current reimbursement mechanism is **not remarkably flexible**: for a medicine purchase to be reimbursed through the SHI scheme, patients need to go through a system of referrals that ultimately gets them to a hospital, where the medicine is prescribed and only then eligible for refund. This limited flexibility means that the system can often struggle to meet the pharmaceutical needs of the entire population, especially of those who suffer from chronic diseases and live in remote provinces. **Rethinking the way the reimbursement system is conceived – and gearing it towards obtaining a prescription at primary care instead of hospital level - could greatly benefit equitable access to medicines**.

[11] For some notable provisions of Circular No 32, please refer to https://www.bakermckenzie.com/en/insight/publications/2019/04/vietnams-ministry-of-health-issues-a-new-circular.

2. Viet Nam-EU Health Cooperation: Pharmaceutical Partnership, In Practice

This chapter focuses on pharmaceutical cooperation between Viet Nam and the EU, providing evidence and critical analysis of the role of the EU and the EPCs in partnering with Hanoi to support equitable access to pharmaceuticals in the country.

This section of the paper assesses the status of and drivers behind health and pharmaceutical cooperation between Viet Nam and the EU, and the EPCs. The first part provides a critical overview of how this cooperation has evolved, according to Viet Nam's changing economic status, disease burden and health priorities. The second part of the analysis focuses on access-related and healthcare strengthening strategies implemented by EPCs – inherently linked to the commercial and reputational benefits that companies perceive as connected to the implementation of these strategies.

2.1 From DAH to Pharmaceutical Cooperation: Partnering with the EU to Improve Equitable Access to High Quality Pharmaceuticals in Viet Nam

The EU has been a strong supporter of healthcare and pharmaceutical development in Viet Nam, more specifically through the financing of a significant number of programmes supporting the strengthening of the country's healthcare system. The European Commission (EC) has been the main financer of development assistance for health (DAH) originating from Europe, followed by Member States contributions led by Germany. DAH has been predominantly channelled towards strengthening Vietnam's primary healthcare, generally taking a disease-specific approach. The support provided has been both financial and in-kind, focusing on capacity building in infrastructures and for healthcare professionals, as well as on improving health education among the population.

Viet Nam's steady economic growth entails that DAH from Europe will be progressively abandoned – and that Viet Nam-EU health cooperation will be shaped according to the country's new economic and health status**.** Moving away from a health development perspective, **a pharmaceutical partnership is a promising option for continuing to jointly support Viet Nam's efforts to meet health demands with world-class quality services and products.**

The EU has proven to be a longstanding partner for Viet Nam in its commitment to accelerate access to high-quality pharmaceuticals in the country**, cooperating with Viet Nam in the realm of research and development (R&D)**, especially on neglected and orphan diseases. In this regard, at the regional level the establishment of the Southeast Asia-Europe Joint Funding Scheme for Research and Innovation (JFS) in 2017 represents a significant development in EU-ASEAN cooperation for health innovation for AMR and

Emerging Infectious Diseases.[12] Another area where fruitful EU-Viet Nam cooperation can be witnessed is NCDs. Two relevant projects financed by the EC targeting Viet Nam have been the FRESH AIR project, launched in 2017 – providing evidence-based knowledge for an improved prevention, diagnosis and treatment of lung diseases[13] – and the SUNI-SEA project in 2019 – providing evidence-based strategies for effective prevention and management of diabetes and hypertension.[14]

Regulatory capacity building represents another facet of the EU-Viet Nam partnership in fostering pharmaceutical access. The EU has closely cooperated with Viet Nam towards the improvement of the country's pharmaceutical regulatory framework, easing the access to high-quality medicines for the local population. The EU has been a pivotal partner in Viet Nam's journey towards the alignment with international standards, supporting the country's integration within the global pharmaceutical market, jointly stimulating foreign investment. With the Vietnamese administration progressively recognising and adopting international standards set by regulatory bodies such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), the EU supported the adoption of internationally-recognised benchmarks to improve supply and distribution chains for pharmaceuticals. This process is aimed to ensure standards are in place to incentivise the development and registration of safe, effective and high-quality medicines.

Significant advancements in Viet Nam's regulations related to the pharmaceutical industry, such as the above-mentioned Pharma Law in 2016, have been influenced by the shared objectives identified during the negotiations that have led to the signing of the EU-Viet Nam FTA.[15] **The benefits of these regulatory progresses will not be limited to those pharmaceutical companies headquartered in Europe, but will be felt across the entire pharmaceutical industry, including Viet Nam's.** The FTA itself represents a step forward in EU-Viet Nam pharmaceutical cooperation, a display of the health-in-all approach undertaken by both parties. This agreement should improve not only Viet Nam's regulatory capacity, but also the affordability of pharmaceuticals, eliminating import tariffs for medicines, while encouraging joint procurement for medicines and vaccines. Thanks to the implementation of the FPA & IPA, signed in February 2020, European and Vietnamese institutions expect pharmaceutical companies based in Europe in particular to intensify their operations in Viet Nam in the future, thereby scaling up their business while at the

[12] For more information: https://www.sea-eu-jfs.eu/health

[13] For more information: https://www.gacd.org/research-projects/lung-diseases/ld04
[14] For more information: https://www.gacd.org/research-projects/diabeteshypertensionscale-up/su02.
[15] From the interviews with Mathieu Fitoussi, GM Servier VN., and with Dan Millard, GM VN.

same time generating a positive impact on the availability of quality pharmaceuticals in the country. The main highlights of this FTA include that (i) pharmaceutical products traded between Viet Nam and the EU will enjoy duty-free status; (ii) EPCs will be allowed to establish FIEs in Viet Nam; (iii) EPCs will have legally secured market access to half of the governmental procurement of pharmaceuticals.

Building on the regulatory progresses obtained since the 2016 LoP, the FTA has the potential to ease the flow of cutting-edge pharmaceutical innovations from Europe – but also from elsewhere – to Viet Nam. This both through the abolition of duty fees and clinical trials, ought to make products more affordable, as well as through the reassertion of a legal framework, set forth by Viet Nam in accordance with WTO standards and EU demands, allowing for the establishment of FIEs with import and trading rights. Nonetheless, further monitoring work is needed to ensure that, within the 2-year implementation period, the provisions included in the FTA effectively translate into action. Implementation challenges in the establishment of FIEs with import rights have been strongly emphasised by the representatives of pharmaceutical companies interviewed for this paper. The EU should monitor Viet Nam's adherence to the commitments made, guaranteeing the right of pharmaceutical companies to expand their onshore operations as jointly agreed, thus supporting European contributions to improved access to pharmaceuticals in Viet Nam.

Last but not least, **a closer cooperation and best practices exchange between Viet Nam and Europe has the potential to boost the position of the Vietnamese pharmaceutical industry vis-à-vis the global market**. Today, Viet Nam is not only becoming an increasingly attractive FIE destination for foreign pharmaceutical companies, but is also climbing the ladder as pharmaceutical manufacturer, due to a number of factors that this paper has discussed above in section 1.3. Thanks to the effective choices made by the Vietnamese administration and a closer partnership with the EU, Vietnam's domestic pharmaceutical industry is now able to better ensure equitable access to medicines in the country than ever before – due to the adherence to EU-recognised GPs ensuring the safety and quality of domestically produced generics.

2.2 (European) Pharmaceutical Companies in Viet Nam: the 'Ace in the Hole' for Enhanced Pharmaceutical Access and Healthcare System Strengthening

EPCs – namely, pharmaceutical companies with headquarters in European countries[16] – have been setting up their operations in Viet Nam since the 1990s, and in a growing

[16] This paper's focus on EPCs – narrowing the analysis to pharmaceutical companies whose headquarters are in Europe – stems from the necessity to find a specific angle of analysis and, consequently, to produce guidelines that are specifically relevant to European stakeholders. Given the extremely complex and multinational nature of pharmaceutical supply chains, the author acknowledges the limitations of such approach and definition. Nonetheless, the scope of the analysis and guidelines provided by the paper is intended to stimulate action from European and Vietnamese institutions in support of constructive dialogue and positive developments in Viet Nam's healthcare and pharmaceutical sector at large. From an industry perspective, the call for greater

number since the 2000s. These companies have been primarily importing their products to the country and, in some cases, invested in joint ventures with local manufacturers. Companies' profiles and portfolios are diverse: Small and Medium Enterprises (SMEs) compete with pharmaceutical giants, with some focusing on the generic market and others on brand-name products. Some EPCs focus on treatment of infectious and/or communicable diseases, with products such as antibiotics, antiviral and anti-parasitics, while others focus on specific NCD-related products – with areas of treatment spanning from oncology to cardiovascular diseases, diabetes, chronic respiratory diseases and urology, just to name a few.

Pharmaceutical companies – domestic or foreign – are a fundamental set of players in improving equitable access to high-quality medicines and strengthening the healthcare system in Viet Nam. They can, should, and often do contribute to enhanced access in different ways, which are primarily contingent to the respective company's product focus.

When specifically assessing EPCs active in Viet Nam, a diverse picture emerges: EPCs importing generic products to Viet Nam contribute to equitable access to high-quality pharmaceuticals by joining domestic manufacturers in providing the local population with access to pharmaceutical products that are not only cost-effective, but also developed at the highest level of safety, quality and effectivity, being manufactured according to European standards on GMP. EPCs importing generics to the Vietnamese market, in the same way as their domestic counterparts, inherently support availability, quality and potential affordability of pharmaceuticals in the country. Nonetheless, their impact on access is limited: the major limitation lies in the nature of their business and resources not allowing them to implement longer-term access strategies, such as engaging in building local capacity and disease management programmes, that in turn carry benefits to the overall healthcare system.

Innovators more than mere producers, pharmaceutical companies focusing on brand-name products are the actors to reckon in the global efforts to guarantee that innovative, high-quality medicines are available and affordable to all. These companies also tend to have more resources to invest and knowledge to share in partnerships with local and international actors to jointly work towards a more effective healthcare system. In Viet Nam, these companies have been engaging with a growing number of actions intended to make their products more easily available to the local population, taking into account the widening income gap resulting from Viet Nam's economic growth, income disparity – and

contributions to healthcare strengthening and action to enhance access to pharmaceuticals in the country – as well as the benefits resulting from developments in the healthcare and pharmaceutical systems – go beyond pharmaceutical companies with European headquarters.

the consequent differences in purchasing abilities among the population. **Improving access to medicines has a strategic significance for these companies, that plays out in reputational and commercial terms.**

A first set of access-related strategies is connected to the specific company's ability to balance between their international reputation as global health actor and need for financial revenues. Foundations such as the Access to Medicine Foundation have taken **companies' practices surrounding intellectual property rights** (IPRs) as criteria to evaluate a company's good practice in expanding pharmaceutical access. The way pharmaceutical companies focusing on patented drugs make use of IPRs can in fact be detrimental to equitable access to medicines – and is an aspect that needs to be monitored so as to ensure that companies effectively comply with their commitments. Among these access strategies, we find non-country specific practices such as the company's support of Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibility and overall patent transparency, together with country-specific commitments such as – bilateral or multilateral – voluntary licensing, patent pooling and registration filings. These practices result in significant, long-term improvements on the availability and affordability of innovative products, making them available on the generic market. On the other hand, such practices also negatively affect the company's ability to retain market monopoly on given products. Therefore, progress in this area has been slow across companies, products and countries (AMF, 2019).

To make sure that European and international pharmaceutical companies enhance their transparency regarding IPR and their access-related strategies in this realm, **researchers from governmental and non-governmental institutions** concerned with the access-to-medicine field **should further shed light on companies' actions regarding voluntary licensing, patent pooling and registration filings**. This way, they would effectively expose companies and push them to take action to enhance market competition and, consequently, improve the availability and affordability of medicines. This applies to Viet Nam as well as to other LMICs that could benefit from companies' greater international exposure and pressure regarding their good practice in IPR transparency, as well as issuing of voluntary licenses on patented medicines to local and generic manufacturers.

Another set of reputational access-related strategies fall into the CSR category, intended to enhance the company's public profile in Viet Nam. **Access-related CSR strategies** are frequent for infectious and communicable diseases, as well as for NCDs treatment. When the latter is the case, these access strategies also carry business benefits for the company, as they allow the local population to familiarise with a company's product. Such product placement strategies take place as product donations and disease-specific patient

assistance programmes (PAPs), aimed at making a given treatment available for a patient in financial need.

EPCs in Viet Nam have a strong presence in terms of both donations and PAPs. For instance, from 2005 to 2019, the Swiss Novartis implemented the Glivec International PAP (GIPAP) in Viet Nam, fully covering the expenses for Glivec, a cancer medication, for patients enrolled in the NHI for less than 36 months. From 2010 to February 2020, Novartis implemented a similar programme to cover the expenses for this product for patients enrolled for longer than 36 months, with Health Insurance Funds covering 40% and Novartis 60% of the cost (VIR, 2020). Another good illustration is the German Bayer, that has since 2016 sponsored a PAP managed by Bright Future Viet Nam, partially funding oral cancer treatments for liver and kidney cancer patients in financial need.

These strategies are undoubtedly positive but to a limited extent, as they only benefit access in the short term and on a case-to case basis, without stimulating relevant improvements in the overall pharmaceutical and healthcare system.

When enhancing access to their products is seen as creating business potential – i.e., long-term increases in sales volume for a company even though products are sold at a lower price –, companies tend to take a more horizontal approach. **Access-related business strategies** are more widespread for products designed to treat NCDs and chronic diseases in general – since treatments for these diseases guarantee companies greater financial revenues in the long run. These strategies encompass the adoption of **inclusive business models**, such as differential pricing strategies, as well as **disease-management initiatives** in line with the company's portfolio, that expand access to pharmaceuticals in the long run. Disease-management initiatives especially focus on capacity building, training of local personnel and health education of the local population, so as to favour early diagnosis, effective prescription and treatment adherence.

The shifting disease burden translated into a growing number of such initiatives in Viet Nam, often in support of the National 2015-2025 NCD Strategy whose objective is to strengthen NCD management at the community level. For instance, from 2016 to 2018 the Novartis Foundation implemented the pilot Ho Chi Minh Communities for Healthy Hearts Programme, to provide healthcare professionals at community level with people-centred healthcare solutions to prevent and treat hypertension in four poor districts in Ho Chi Minh City.[17] Thanks to the success of this pilot programme, the Novartis Foundation partnered with Access Accelerated, PATH and the Vietnamese MOH to implement a relative programme in 2019, Communities for Healthy Vietnam, that covers the whole nation and

[17] Information retrieved from the website of Novartis, at: https://www.novartis.com/news/media-releases/novartis-foundation-and-partners-launch-innovative-hypertension-program-vietnam

extends its scope to other NCDs, providing community-based care models in target districts for hypertension and diabetes.[18]

The French company Servier represents another compelling example of the EPCs' engagement with long-term strategies in support of both better access to quality treatment and healthcare system strengthening. The First Day Project, implemented by Servier in collaboration with the Vietnamese Heart Association and Diabetes Association, aims to improve early intervention and management of diabetes and hypertension by healthcare professionals, and to stimulate treatment adherence among patients. To do so, the Project successfully created online platforms where patients can easily retrieve information on the conditions and the appropriate treatment guidelines, besides getting in contact with healthcare professionals. As part of the Project, whose financial cost was entirely covered by Servier, training to healthcare professionals on NCD treatment was also provided.[19]

[18] Information retrieved from the website of Access Accelerated, at: https://accessaccelerated.org/our-work/primary-care/vietnam/

[19] From the interview with Mathieu Fitoussi, GM Servier VN. For more information on the First Day Project: www.ngaydautien.vn

3. Policy Recommendations: Towards a Collaborative Partnership for Health

The EU and Viet Nam could harness the strong links they have built in healthcare and pharmaceuticals to create a **collaborative partnership with the pharmaceutical industry**, with the aim of jointly strengthening Viet Nam's healthcare system and improving equitable pharmaceutical access in the country.

The private sector has become a driving force for innovation and development. In the pharmaceutical sector in particular, making innovation available to the wider public is growingly accompanied by ethical and social considerations. Due to reputational and commercial payoffs, pharmaceutical companies focusing on patented drugs are stepping up their roles as global health actors. **Companies have a responsibility to support the progressive realisation of the right to health** – and they can do so through committing their resources to system strengthening initiatives, health education, as well as to enhance availability, affordability, and quality of medicines.

3.1 General Recommendations

Both the EU and EPCs should invest more in **local capacity building and R&D development** in Viet Nam.

- They should scale up their support to the country's efforts in boosting local production of raw materials, APIs, vaccines and treatments for rare diseases.
- Viet Nam could provide incentives for EPCs engaging with scientific cooperation in R&D. Prolific partnerships could be created, based on knowledge transfers, scholarship programmes and other forms of collaboration between EPCS, Vietnamese universities and research centres. This new focus on R&D cooperation could support the long-term enhancement of the Vietnamese pharmaceutical industry, creating an environment where high-tech innovation and equal partnerships can thrive.

In consultation with the Vietnamese government and European competent bodies such as the European Medicines Agency (EMA), DG TRADE and DG SANTE, international and European pharmaceutical companies could **formulate clear commitments to expand pharmaceutical access and strengthen the healthcare system** in Viet Nam. Shared, operational standards should be created to measure and monitor the extent to which companies' practices fulfil these commitments.

Now that Viet Nam's economy in general and its pharmaceutical industry in particular are entering a more mature stage, and that EPCs will increasingly move on-shore with FIEs, the Vietnamese administration could **formulate a national strategy to promote CSR**.

This could bring together the government, civil society and the private sector under the umbrella of promoting good governance, to develop businesses that respect the environment and support a stable economy and an equitable society. Ensuring that both domestic and foreign companies in Viet Nam operate in accordance with Vietnamese environmental, labour and social standards and priorities is of paramount importance to ensure sustainable and ethical development in the country.

- It is important that this strategy is developed and implemented following the concept of local ownership, so to ensure that companies align to Vietnamese standards and needs, and not the other way around.
- The national strategy to promote CSR could build on existing CSR projects and focus equally on big companies as well as SMEs, that tend to be less active on CSR than international and multinational companies.
- This strategy could serve as a pivotal first step towards the creation of a **national CSR legislation**. This legislation could adopt annual mandatory reporting as a key element to monitor that companies effectively comply with their commitments.

In line with the public awareness and professional training objectives already put forward by the Vietnamese administration (see, among others, the scheme 'Incentivising Vietnamese people to use Vietnamese medicines'[20] and Decision No. 4815/QD-BYT, 2019, on the basic competencies of Vietnamese pharmacists), Viet Nam, the EU and EPCs could **invest resources to enhance health education among the population** – especially in relations to the safe use of pharmaceuticals and the importance of treatment adherence.

- Grassroots health education campaigns focusing on empowering the most vulnerable segments of society should be further boosted. Such campaigns should specifically highlight the importance of cost-effective pharmaceutical use and purchasing behaviour.
- Viet Nam's objective to accelerate the development of human capacity for health and pharmacy could be achieved with European support, through educational schemes and targeted investments.

Greater trust and open dialogue should be stimulated between Vietnamese institutions, local and foreign pharmaceutical companies.

In this regard:

[20] For more information see: https://moh.gov.vn/home?p_p_id=101&p_p_lifecycle=0&p_p_state=maximized&p_p_mode=view&_101_struts_action=%2Fasset_publisher%2Fview_content&_101_type=content&_101_urlTitle=hoi-nghi-tong-ket-e-an-nguoi-viet-nam-uu-tien-dung-thuoc-viet-nam-

- A dialogue platform between the Vietnamese government, the local and foreign pharmaceutical industry should be created involving not only companies and institutions, but also local wholesalers and manufacturers. The 2005-2008 EU Pharmaceutical Forum[21] could be used as a model.
- Such forum could serve as a pilot for an ASEAN Pharmaceutical Forum, ascertaining that regional cooperation and coordination in health and pharmaceuticals to be enhanced.
- Relevant EU institutions could serve as facilitators of this process, providing financial and technical assistance in support of such consultative processes for legislative development.

Further constructive dialogue and experience sharing between the EU and Viet Nam in the realms of healthcare and pharmaceuticals would help finding additional common grounds between regulatory systems and production standards in Viet Nam and the EU. The **progressive harmonisation with international standards and practices** would be beneficial to Viet Nam, not just in terms of enhanced domestic access to medicines but also for the country's integration in the global pharmaceutical supply chain. This way, Viet Nam could aspire to play a greater role as exporter of raw materials, semi processed and finished products to other ASEAN member and to EU countries, among others.

3.2 Recommendations for Healthcare System Strengthening

Building on enhanced consultative processes, Viet Nam and the EU, together with local and foreign pharmaceutical companies and relevant stakeholders, could **jointly identify additional areas of the healthcare system that need strengthening**. The parties could find shared objectives and formulate clear, measurable frameworks and investment plans for joint action. Such frameworks should build on the parties' complementary experiences and strengths, prioritising local capacity building, knowledge and technology transfer, so to ensure sustainable development.

The EU could support Viet Nam with financial resources channelled to **strengthen the country's public primary care**. Building a strong, resilient system of primary care at community and district level would result in short and long-term improvements in Viet Nam's health outcomes.

Viet Nam could find in the EU a partner with whom exchanging knowledge relevant to the **rethinking of the reimbursement system connected to its SHI**. The EU boasts an impressive variety of reimbursement systems, that could potentially serve as inspiration for Viet Nam both for healthcare services and pharmaceutical purchases. Overall, Viet

[21] A high-level forum bringing institutions, industry, healthcare professionals, patients and insurers together to find solutions to public health issues regarding pharmaceuticals, while also ensuring competitiveness and the sustainability of national healthcare systems – could be used as a model.

Nam's reimbursement system could be made more flexible, with prescription possible at the level of primary care, and the possibility to top up insurances, so to better serve the health needs of both the poorer and richer strata of the population. This would produce several benefits: for instance, it would limit purchasing from private pharmacies and health tourism from Viet Nam to other ASEAN countries – eventually producing additional revenues to be reinvested in domestic health strengthening.

In partnership with the EU and other relevant international institutions, Viet Nam could **progressively restructure the way its healthcare system is financed**. Now that Viet Nam's graduation from DAH draws closer, the EU should accelerate its support to Viet Nam's shift towards sustainable health financing. In this regard, private healthcare and health insurance providers might be further integrated in the system, under government's monitoring, to broaden financing sources. Opening up to FIEs connected to the health industry could also be beneficial, providing additional fiscal revenue to finance public health.

3.3 Recommendations for Improved Availability of Pharmaceuticals

The Vietnamese administration should continue to **invest and prioritise the development of a strong local pharmaceutical industry**. The latter is in fact the primary relevant actor in ensuring that equitable access to safe and high quality medicines is available to the Vietnamese population.

International and European pharmaceutical companies in particular must **do more to ensure timely access to innovative products in Viet Nam**. Detailed commitments regarding the registration of their products in the country should be formulated, aligning their registration filings with the country's health needs. Companies should manage intellectual property in a more access-oriented way, improving patent transparency and increasing the number of compounds available for voluntary licensing to generic manufacturers.

To guarantee and boost the fast and consistent availability of medicines, **the Drug Administration of Viet Nam (DAV) needs restructuring**. Viet Nam could invest additional resources to ease the administrative burden carried by this office, while simultaneously stepping up its capacities for processing registration dossiers – creating additional units for those areas where the administrative load is heavier and more personnel is necessary. The EU could provide financial and technical assistance for this restructuring, so that registration filings for new products as well as visa renovation can be processed faster. Increases in registration fees for pharmaceutical companies could also be introduced, channelling these additional revenues towards the restructuring of the DAV.

Progressively **lifting the remaining administrative and trade barriers** that limit fast and consistent availability of innovative pharmaceutical products of foreign origin on the market, Viet Nam would achieve greater access-related advancements. Registration filings and visa renewals for foreign pharmaceutical products in Viet Nam could be made more efficient. The current system of visa renewal – where market authorisation must be renewed every five years – could be rethought, implementing longer-term arrangements coupled with closer product monitoring. The removal of the additional requirements for CPPs, beyond WHO standards, would greatly benefit the possibility of the Vietnamese population to quickly get access to innovative treatments.

Viet Nam could **rethink the way it formulates and distributes its LEMs, together with the way pharmaceuticals are procured and distributed by hospitals**. A greater alignment of Vietnam's LEMs with the one formulated by the WHO, published regularly and with constant updates regarding bioequivalent products (to incentivise the procurement and consumption of locally-produced generic medicines), would significantly improve the availability of medicines. The focus could be set on making prescription and pharmaceutical purchase through public channels available at commune and district-level facilities.

3.4 Recommendations for Greater Affordability of Pharmaceuticals

Pharmaceutical companies focusing on patented drugs should **step up their adoption of affordability strategies**. Companies should increasingly adopt differential pricing strategies tailored at both the national level, as well as according to different purchasing abilities of the population. Differential pricing strategies should be already included at the R&D stage, so as to ensure that innovative treatments are available to a larger part of the population. Greater patent transparency and voluntary licensing would create a competitive market environment where medicines are made more affordable to all.

To make sure that medicines are equally accessible at an affordable cost to all patients, Viet Nam, in partnership with the EU and pharmaceutical companies, should **create the right environment for price competition**. Comprehensive price management strategies should be implemented to monitor pharmaceutical prices, limiting cost increases that would hamper affordability. Viet Nam could find alternative ways to formulate pricing guidelines for pharmaceuticals – no longer basing them on comparative pricing bands, as these allow for price inflation. Experts from the EU hold relevant expertise to provide technical support in this process. Especially when a differential pricing strategy is implemented by a pharmaceutical company, Viet Nam could partner with companies to find creative monitoring solutions, so as to ensure that products do not undergo unjustified price growths along the distribution chain.

3.5 Recommendations to Ensure the Quality of Pharmaceuticals

Viet Nam and the EU could further **enhance information and best practices sharing in the realm of pharmaceuticals**, supporting the development of global best practices in pharmaceutical production and distribution. A greater collaboration between the Government of Viet Nam and the EMA could be of great benefit, realising knowledge transfer in support of good practices and quality control along the pharmaceutical supply chain.

To better monitor product quality at the registration and marketing authorisation stage, Viet Nam could channel resources to **create quality testing units and dossier review units in the DAV**. This is in line with the List of Concentrated and Preferential Investment Project promulgated with the Decision No. 68/QD-TTw dated January 10, 2014.

To better monitor post-marketing product quality and curb the circulation of counterfeit drugs, Viet Nam could **enhance** its **cooperation with** both **local and foreign pharmaceutical companies,** as well as with the **other actors** along the pharmaceutical supply chain. The creation of a National Pharmaceutical Database System is a positive step in this direction. In particular, incentives could be introduced for those companies investing in increased local capacity building for quality assurance, pharmacovigilance, and detection of falsified medicines – i.e., training of local inspectors, creation of local testing laboratories, introduction of anti-tamper devices and traceability technologies, and the formulation of suitable solutions to verify products at the point of dispensing.

3.6 Final Remarks

A collaborative partnership between Viet Nam, the EU and their respective pharmaceutical industries to boost healthcare and access to medicines in Viet Nam is a compelling solution to bring all relevant stakeholders on the same page – and in the same room. This new partnership could be built on enhanced dialogue, better monitoring and greater exchange of knowledge, experience and resources. Positive outcomes are at stake for all parties involved – but the greater benefits of this new collaborative chapter would eventually be reaped by the Vietnamese population.

This study provides an initial analysis of the current situation. Further research in this field would be of great help in **assessing how health and pharmaceutical development in Viet Nam can be further boosted**. If the discussion is to be moved forward, a better understanding of the **role of health and pharmaceutical cooperation in the relations between Viet Nam and the EU** needs to be developed. Considerably more research will need to be carried out to determine and monitor:

- the development status of Viet Nam's pharmaceutical industry;
- the role played by EPCs in strengthening healthcare and improving equitable access to medicines now that they are expanding their operations in Viet Nam, and
- how companies would comply with possible national CSR strategies.

More broadly, research is also needed to **determine how a strong, long-term cooperation between Viet Nam and Europe can be secured** in these realms.

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