Policy Brief, 03/2020

EIAS European Institute for Asian Studies

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

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Published in May 2020

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 policy brief calls for a collaborative partnership between institutions and pharmaceutical companies, with the aim of guaranteeing equitable access to pharmaceuticals to the Vietnamese people.

This policy brief summarises the findings of in-depth research, published in a more extensive research paper under the same title, 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

List of Abbreviations and Acronyms

AMR – Anti-Microbial Resistance

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

GIPAP – Glivec International PAP

GMs – General Managers

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

OOP – out-of-pocket

SMEs – Small and Medium Enterprises

PAPs – Patient Assistance Programmes

PCA – Partnership and Cooperation Agreement

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

Executive Summary

Viet Nam and the 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 UHC thanks to the establishment of a government-reimbursed national scheme, the 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 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 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 IPA, important building blocks of the EU-Viet Nam 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**.

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.

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.

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 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'[1] 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:

[1] 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[2] 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.

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

[2] 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.

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.

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.

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.

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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