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VIETNAM - 2019

HEALTHCARE



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I. Overview:

1. Pharmaceuticals:

Due to changes in government policies and development in the domestic regulations of imported drugs, Vietnam’s pharmaceutical sector has grown significantly in the last decade. Although regulations on advertising and clinical trials can still create obstacles for sellers, looking to break into the market, with the right information Vietnam offers many opportunities for potential suppliers.

According to the 2018 Business Monitor International report, the Vietnam healthcare market had a value of USD17.4 billion in 2018. At a per capita level, spending is expected to double from USD170 in 2017 to USD400 in 2027. Meanwhile, the country’s pharmaceutical market had an estimated a revenue of USD5.9 billion in 2018, an 11,7% increase from the previous year, which makes Vietnam the second largest medicine market in the South East Asia¹. The market is set for double digit growth within the next five years, according to Vietnam Report Company (VNR). The average spending of Vietnamese people on drugs rose from USD22.25 in 2010 to USD37.97 in 2015, and doubled to USD56 in 2017 (figure 1). The average growth rate of spending on drugs was 14.6% during 2010-2015 and is set to maintain a rate of at least 14% until 2025².

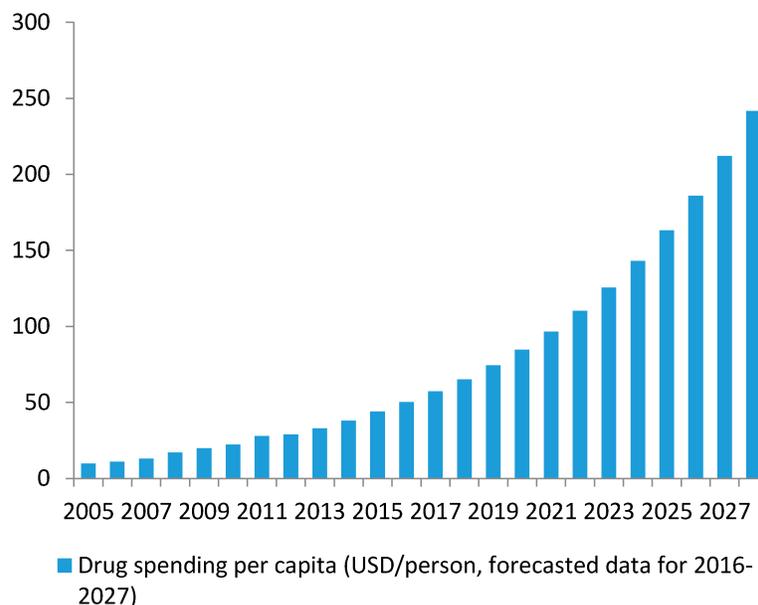


Figure 1: Drug spending per capita

Source: “Pharmaceutical Industry in Vietnam: Sluggish Sector in a Growing Market, Antonio Angelino”, Do Ta Khanh, Nguyen An Ha and Tuan Pham, 2017, Int. J. Environ. Res. Public Health 2017

Vietnamese drug manufacturers are able to meet half of the total medicines market demand, while imports cover the remaining half.³ In addition, approximately 60% of pharmaceutical end products, 90% of active pharmaceutical ingredients, and most raw materials for the production of pharmaceuticals are currently

¹ Vietnam Healthcare and Pharmaceutical report– Q2 2018, Business Monitor International, 2018.

² Vietnam medicine cost put at VND1.3 million per capita, The Saigon Times, Dec 27, 2017, <https://english.thesaigontimes.vn/57722/Vietnam-medicine-cost-put-at-VND13-million-per-capita.html>.

³ Sophia Harris, Vietnam’s Growing Pharmaceutical Market, Vietnam Briefing, April 13, 2018.

imported⁴. In recent years, the authorities have stepped up their efforts to reduce the country's reliance on imports. As part of their 2020 strategy, authorities intend to have 80% of domestic pharmaceutical demand met by local drug manufacturers through measures such as tendering preferences.⁵

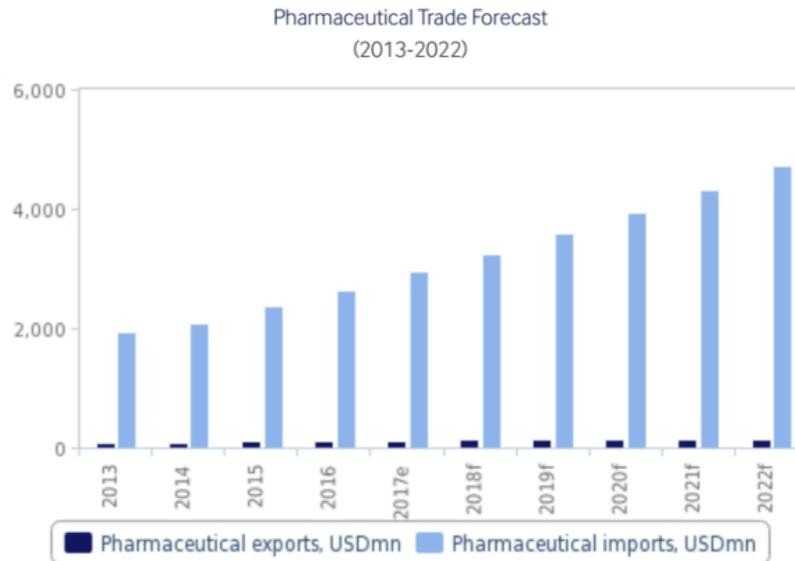


Figure 2: Pharmaceutical Trade Forecast (2013-2022)

Source: United Nations Comtrade Database DESA/UNSD, Fitch Solutions

2. Medical devices:

The Vietnamese medical equipment market is the ninth largest market in the Asian Pacific region⁶. Vietnam is growing as a manufacturing location for medical device companies and exports have been posting consistent growth. According to Ministry of Health (MOH), the country's medical equipment market is expected to enjoy a growth rate of 18-20% in 2016-2020, but more than 90% of medical equipment is imported from other countries, mainly from Japan, Germany, the United States, China and Singapore. Medical products from these markets make up 55% of Vietnam's total medical equipment imports. Meanwhile, domestic enterprises, currently comprising of 50 medical equipment manufacturers, which are licensed by the MOH, account for only 10% of the local market share.⁷

In 2017, according to the HCMC Medical Equipment Association, Vietnam spent USD1.1 billion on medical equipment imports, which is mainly diagnostic imaging equipment such as X-ray, ultrasound, magnetic resonance imaging and computed tomography scanners, as well as equipment used for surgery, endoscopy, sterilization, testing and medical waste treatment.

⁴ Ministry of Planning and Investment, Healthcare and medical services, Foreign Investment Agency, Last accessed Feb 24, 2019.

⁵ EY Life science report: Asia (Pacific Asia, India, Japan), EY, March 2017.

⁶ Vietnam Medical devices report– Q2 2018. BMI, Business Monitor International, 2018.

⁷ Vietnam imports large volume of medical equipment, The Saigon Times, Jul 26, 2018, <https://english.thesaigontimes.vn/61530/vietnam-imports-large-volume-of-medical-equipment.html>.

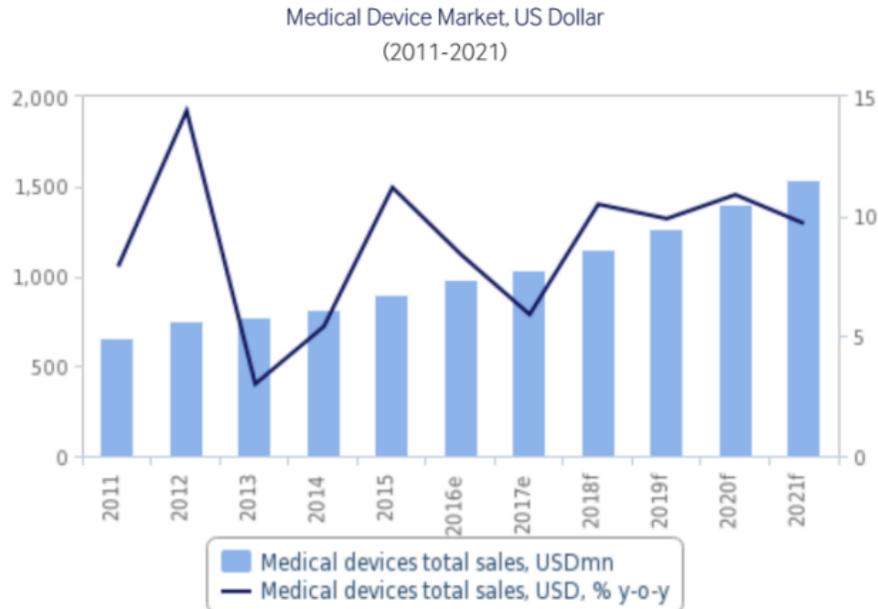


Figure 3: Medical Device Market (2011-2021)

Source: National Statistics, Fitch Solution.

II. Opportunities

The demand for improved healthcare is rapidly expanding as a consequence of the high economic growth, the rising income per capita, increasing urban population, an aging population as well as the opportunities provided by healthcare insurance schemes.

According to the Asian Development Bank, Vietnam is in the top 3 countries with the fastest economic growth in Asia. This can be seen through Vietnam’s gross domestic product (GDP) increasing to 7.08% in 2018, the highest in the past 11 years. Strong economic growth, enhanced personal income and rising health awareness both favourable conditions for increased spending on healthcare in general.

Additionally, over the last two decades, Vietnam population has expanded from 72 million people in 1995 to over 95 million people⁸ in 2019 which has increased the market size. According to the World Bank, urban areas in Vietnam have developed spatially at 2.8% per year, among the fastest growth rates in the Asian region. In these contexts, the growth of a new urban middle-class will induce changes in community behaviours and consumption patterns and will positively affect the demand for healthcare and pharmaceutical products.

The Vietnam population officially entered an ‘aging phase’ in 2017⁹ and is among the most rapidly aging countries in the world, which will force authorities to spend more money, to improve healthcare services to take better care for senior citizens. The proportion of older people in the total population has increased to

⁸ World bank, <https://data.worldbank.org/country/vietnam>.

⁹The ageing population in Viet Nam: Current status, prognosis, and possible policy responses, United Nations Population Fund, July 2011.

11.9%, and one in six people was over the age of 60 in 2017¹⁰. As a result, public, provincial-level hospitals funded by the governments are undergoing upgrades of their facilities and opening new departments for specialty treatment. The government also aims to bring insurance coverage to 100% of the population by 2030,¹¹ with additional initiatives also being developed to further enhance health care delivery.

Such developments are creating new opportunities not only for medical devices but also pharmaceuticals producers in Vietnam. However, the local production of medical equipment and pharmaceuticals have not been able to meet demand. Local producers have only been able to supply basic medical supplies such as scissors, rubber health products, scalpels, hospital beds and other disposable supplies which according to MOH means 90% of medical devices in Vietnam need to be imported. In terms of pharmaceuticals, domestic drug firms focus mostly on producing generic products and other simple areas of drug production, as they lack research and development capabilities as well as the ability to invest in new compounds. Consequently, much of Vietnam's spending on pharmaceuticals is on imports. The MOH data shows that the country's drug imports last year increased by 8.8% year-on-year to US\$3.7 billion. Therefore, the government is looking to the private sector to meet some of the demands being placed on the industry, designating healthcare as one of 17 sectors open to foreign investment in January 2016.

III. What are the challenges?

Pharmaceuticals

1. Regulation:

Vietnam is not a market for inexperienced exporters. Many pharmaceutical companies have to deal with numerous documents due to the complex national regulations. In Vietnam, the government requires all new drugs to go through registration and clinical trials, before they can be sold to the public.

- **Clinical trials:** These trials have very little ability to actually judge the effectiveness of a drug, but create a waiting period during which the drugs cannot be sold. Nevertheless, under Vietnam Law on Pharmacy, each product approval lasts only five years and pharmaceutical firms will have to re-apply for the licence at least six months prior to the expiry of the registration. The process of renewal can take from eight months to over a year, restricting a pharmaceutical firm's access to the Vietnamese market.

- **Patent Registration:** Many companies face delays in terms of patent registration approvals, limiting the effective term of patent protection due to specifically insufficient personnel capacity. Besides, companies also face patent enforcement issues after patent approvals. Pharmaceutical Research and Manufacturers of America (PhRMA) highlighted weak regulatory data protection in the country, which makes it easier for generic drug makers to make use of the innovator data, during their marketing approval application.

2. Distribution:

As part of the WTO membership, foreign enterprises have been given the right to open branches in Vietnam and to import medicines directly. However they are prohibited from distributing their products without a license and need to cooperate with a domestic wholesaler.

3. Counterfeit drug issues:

¹⁰ Talk-show on the International Day of Older Persons 1/10/2018: "Responding to population ageing in Viet Nam: the Way Forward", the United Nations Population Fund Vietnam, 1 October, 2018. <https://vietnam.unfpa.org/en/news/talk-show-international-day-older-persons-1102018-responding-population-ageing-viet-nam-way>.

¹¹ Health coverage improves Vietnam experiences demographic changes, Oxford business group, 20 Mar, 2017, <https://oxfordbusinessgroup.com/news/health-coverage-improves-vietnam-experiences-demographic-changes>.

Since Vietnam became WTO's member, a number of steps to increase IP protection and the country's patent structures have been ratified by the administration, which made some improvements to the country's intellectual property in drugs and further requirements are being imposed by the CPTPP and the EU-Vietnam Free Trade Agreement, if ratified. However, illegal copying, fake and low-quality drugs remain commonplace. Part of the problem is because the government has few resources to tackle the problem. Therefore, the majority of drug sales in Vietnam are achieved not through regulated pharmacies but through private dealers that handle drugs worth an estimated USD450mn per year¹².

Medical devices:

1. Regulation restriction:

Since Vietnam medical device production is unable to meet demand, Vietnam government encourages the import of medical equipment by incentives such as low import duties and no quota restrictions. However, medical devices still need to be subject to regulation and licensing requirements set by the MOH. Starting in 2017, all medical devices imported into Vietnam have to register for marketing authorization (MA) licenses. Previously, imported medical devices did not require MA licenses.

Additionally, imports of used and refurbished medical equipment are strictly controlled by MOH. Decision 2019/1997/QĐ-BKHCNMT which stipulates that The Ministry of Science and Technology must inspect and certify all imports of used medical equipment. Because of the restriction, local companies are generally not willing to deal with foreign suppliers of used and refurbished equipment. However, MOH will approve the used equipment for donation purposes only.

2. Distribution:

Under Vietnamese law, only business entities registered in Vietnam that have an import license are eligible to distribute medical devices within Vietnam. Therefore, when entering Vietnamese market, foreign medical device suppliers must establish a local office or appoint a local distributor.

IV. Further outlook:

The Ministry of Health has recently issued Decree No.155/2018/ND-CP, which has many positive changes towards cutting procedures and creating favourable conditions for businesses in tenders, drug imports, and others. In terms of the medical device sector, the new Decree 169 slashes some regulations in Decree 36 in line with Resolution No.01/NQ-CP on cutting business conditions, which will ease the business of trading medical equipment. According to the MoH's Department of Medical Equipment and Works, this will create a legal framework for the management of medical equipment, in the new development period, increase international integration while meeting international norms. Additionally, the Vietnam government also encourages foreign investment by putting forward a wide range of incentives for private healthcare sector, such as incentive tax rates (corporate income tax rate of 10% throughout the project life span)¹³ and zero tariff. Thanks to the government's new policies, MOH expects that more and more foreign companies to enter the Vietnam market to cash in on the country's growing medicine demands.

Prescription drugs are expected to dominate over the coming decade, with the biggest focus being on drugs for the treatment of infectious and chronic diseases. On April 2019, the MOH has ordered that all drugstores should be connected to the national medicine database via the Internet. This aims to prevent the sales of drugs without prescription, which has always been common practice in Vietnam. Around 88% of all antibiotics sold in urban areas and 91% sold in the countryside are without prescription¹⁴. Currently, 61%

¹² Vietnam Healthcare and Pharmaceutical report– Q2 2018, Business Monitor International, 2018.

¹³ Vietnam: corporate- tax credit and incentive, PwC, last reviewed Dec 18, 2018, <http://taxsummaries.pwc.com/ID/Vietnam-Corporate-Tax-credits-and-incentives>

¹⁴ The Ministry of Health Database

of over 6000 drugstores in Ho Chi Minh City and 90% of over 4600 drugstores in Ha Noi¹⁵ have linked up to the national database. The MOH insisted that inspection is to be carried out in the near future and non-compliant pharmacies would face the penalty of having their licenses taken away. According to WHO, Vietnam is among the countries with the highest rate of antibiotics resistance. A growing chronic disease burden and rising resistance to antibiotics will continue to be the central driver of Vietnam's healthcare expenditure.

In terms of medical devices, Vietnamese healthcare organizations are in great demand for advanced technology, and advanced laboratory and clinical equipment and information systems for research, diagnostics and treatment are attracting the most interest. In terms of medical specialties, Vietnamese are battling with chronic diseases due to changing lifestyles, aging and rising pollution. Hence, products that supports the research, diagnosis and treatment of pulmonology, cardiology, geriatrics and gynecology will experience growth in demand.

¹⁵ Dat Nguyen, Vietnam cracks down on drugstores selling without prescriptions, VN Express International, April 1, 2019

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