



A Partner in Promoting Health and Wellness in Vietnam

2020 HEALTHCARE COMMITTEE WHITE BOOK

American Chamber of Commerce Vietnam, Ho Chi Minh City and Da Nang



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ABOUT THE AMERICAN CHAMBER OF COMMERCE VIETNAM, HO CHI MINH CITY AND DA NANG HEALTHCARE COMMITTEE

The Healthcare Committee has long been an instrumental part of the American Chamber of Commerce Vietnam, Ho Chi Minh City and Da Nang (“AmCham Vietnam, HCMC and Da Nang”). AmCham Vietnam, HCMC and Da Nang’s Healthcare Committee (“AVHC”) serves as a platform for AmCham Vietnam healthcare members to:

- Network and share best practices;
- Discuss industry and regulatory developments; and
- Identify and advocate for improvements in the delivery of healthcare and healthcare policy in Vietnam



The AVHC also provides leadership to AmCham Vietnam, HCMC and Da Nang on health-related CSR projects. To support the Vietnam government’s efforts to contain the COVID-19 epidemic, in March 2020, the AVHC took the lead in the AmCham Vietnam donation of 250,000 face masks to the frontline health workers. In May 2020, the AVHC coordinated the donation of RNA/DNA extractors and PCR machines to the Ho Chi Minh City Center for Disease Control and Prevention (HCDC). Over the years, the AVHC has organized AmCham Vietnam, HCMC and Da Nang Blood Donor Day and supported AmCham Vietnam members to prepare for health emergencies.

In 2018, the AVHC renewed and refreshed the committee’s mission, vision, and structure to better serve the healthcare needs of Vietnam’s population in order to acknowledge Vietnam’s rapidly developing healthcare service delivery network and increasing healthcare demand, along with the significant growth in trade and investment between the US and Vietnam.

With this mission in mind, the AVHC updated the committee’s Vision Statement, effective as of May 2020:

The American Chamber of Commerce Vietnam, Ho Chi Minh City and Da Nang Healthcare Committee is a key strategic partner for promoting health and wellness and shaping the healthcare industry in Vietnam.

Top Priorities

- Proactive engagement in healthcare policy cooperation
- Share broad expertise of members across the healthcare environment
- Serve as a key facilitator on healthcare for both U.S. mission and Vietnamese healthcare stakeholders
- Information sharing network
- Leadership in healthcare & wellness best practices

By early 2019, the renewal of the AVHC has turned the Committee into one of AmCham Vietnam's most dynamic, active, and well-attended committees. There are more than 40 companies actively involved with this Committee.

A unique aspect of the AVHC, unlike many other industry groups in Vietnam, is broad representation across various segments in healthcare. The diversity of the AVHC results in thoroughly-debated and comprehensive solutions to address Vietnam's healthcare needs with wide support from membership across all sectors. Consequently, solutions and recommendations from the AVHC demonstrate the overall constructive value of efforts and ideas across the group rather than one sector benefitting at the expense of others.

Aiming to facilitate a broad representation and mission of the AVHC, a new structure and leadership team was established for the 2019-2020 tenure:

Leadership Team

Co-Chair:	Chris Blank (Pharmacity)
Co-Chair:	Jonathan Moreno (Diversatek)
Board Liaison:	Minh Nguyen (Aetna)
Vice Chairs by Sub-sectors:	
Medical Devices:	Dr. Ha Nguyen (Medtronic)
Healthcare Providers:	Dr. Mason Cobb (Victoria Healthcare)
Innovative Pharmaceuticals:	Koen Carel Kruijtbosch (Merck Sharp and Dohme)
Retail Pharmacy:	Thien Le (Pharmacity)
Private Insurance:	Minh Nguyen (Aetna)
Laboratory Diagnostics:	Sam Pearl (Diag)
Supporting Industries:	Michael Sieburg (YCP Solidiance)
Secretary/Treasurer:	Luke Treloar (KPMG)
Legal Advisor:	Philip Ziter (Russin & Vecchi)
Government Affairs Advisor:	Samuel Pursch (Vriens & Partners)



INTRODUCTION TO THE AMCHAM VIETNAM, HO CHI MINH CITY AND DA NANG HEALTHCARE COMMITTEE WHITE BOOK FROM THE CO-CHAIRMEN

Thank you for taking the time to read, review, and consider the information from AVHC's inaugural white book. We believe this white book will be helpful to understand the current challenges and opportunities for AVHC members' trade and investment activities seeking to advance healthcare in Vietnam.

We are proud to be a part of Vietnam's healthcare ecosystem as Vietnam has gained worldwide recognition for its excellent handling of the COVID-19 epidemic. The strong commitment from the Vietnamese government to protecting the health of its people will most certainly provide greater momentum to further developing the Vietnamese healthcare system. For its commitment, determination, and leadership, we sincerely express our gratitude to the Vietnamese government.

Members of AVHC do not merely view healthcare as a business opportunity, but also as a commitment to improve society. The membership believes that each person served by Vietnam's healthcare system, public or private, deserves to have access to the best healthcare services possible.

The leadership of the AVHC recognize that our members share common goals to improve Vietnam's healthcare system. Moreover, the AVHC has sought to align our recommendations with goals from the "National Strategy for the Protection, Care, and Improvement of People's Health for the period of 2011-2020 with orientation towards 2030" (Decision 122/QĐ-TTg) from Vietnam's Ministry of Health, such as:

- Improve the quality of medical examination, treatment, and rehabilitation services; reduce the pressure on major hospitals; develop non-public healthcare services and enhance public-private partnership;
- Ensure adequate supply of high-quality medicines, vaccines, medical preparations, blood, blood preparations and medical equipment of quality at reasonable prices to meet people's demand for disease prevention and treatment; manage and use medicines and equipment reasonable, safely, and efficiently; and
- Develop the human resources of the health sector in terms of quantity and quality.

This white book includes sections organized by key industry leaders in the AVHC, namely Medical Devices; Healthcare Providers; Innovative Pharmaceuticals; Retail Pharmacy; Private Insurance; Laboratory Diagnostics; and Supporting Industries. Within each section, we issue recommendations aiming to provide an environment in which Vietnam's healthcare system moves closer toward achieving the goals set forth by the government.

With AVHC's diverse membership, there is a broad spectrum of support covering most aspects of healthcare in Vietnam. There are logically occasions whereby one of our sub-sectors might have an interest in conflict with another sub-sector. However, this white book recommends solutions that all sub-sectors support.

As a committee, we understand that it is important to point out the most critical and timely recommendations to either not lose momentum or to more quickly gain momentum toward achieving the important goals set forth by Vietnam's Ministry of Health. Therefore, as a committee, we have aligned on the top three recommendations. These highlighted recommendations are noted in the Executive Summary.

In addition to the advocacy recommendations, the white book aims to share information about these key industry sectors to identify current trends, opportunities, and challenges as well as highlight how our AVHC members are currently contributing to the advancement of healthcare in Vietnam.

It is our objective that this white book will be updated annually. We are also confident that the AVHC will increasingly be a key partner with Vietnam's policy makers in achieving goals that will improve the health of all people in Vietnam.

For Health,



CHRIS BLANK
Co - Chair



JONATHAN L MORENO
Co - Chair



EXECUTIVE SUMMARY

Vietnam's government and healthcare industry have achieved global recognition for their successful response to COVID-19. AVHC applauds their efforts in prioritizing and protecting the health of those who live in Vietnam.

"We are a key strategic partner for promoting health and wellness and shaping the healthcare industry in Vietnam"

AVHC Vision

As Vietnam's economy has enjoyed impressive growth over the last three decades, its healthcare system has developed and adapted to new challenges. Incomes are rising, life expectancy is increasing, and cities are growing, and with these changes, issues related to health in the population are shifting towards non-communicable diseases (NCDs). In a rapidly developing environment, the Vietnamese government seeks to improve the quality of medical examination and treatment; reduce pressure on major hospitals; promote private sector participation in the health system; develop the quality and quantity of health sector human resources; and ensure adequate and safe supply of medicines, vaccines, and equipment for the benefit of the Vietnamese population as well as those living and traveling in Vietnam.

AVHC members represent a diverse range of industries including medical devices, healthcare providers, innovative pharmaceuticals, retail pharmacy, private insurance, laboratory diagnostics, and supporting industries. Together, we are committed to being a strategic partner for promoting health and wellness and shaping the healthcare industry in Vietnam. Through our investments and activities in Vietnam, AVHC members are increasing access to health products and services as well as promoting international standards of quality. In addition, our companies and staff are active in the community with corporate social responsibility (CSR) efforts to support health and wellness efforts in Vietnam.

The objective of this inaugural AVHC white book is to share information and ideas, showcase the role of our member companies in Vietnam's healthcare landscape, and highlight advocacy efforts that are important to advancing healthcare in Vietnam. We specifically want to address the following three healthcare issues as central to our advocacy position:

1. Ensuring the new Law on Medical Devices Management meet the needs of Vietnam's healthcare system and its supporting industries via consultation with industry stakeholders to ensure it is in harmony with international standards and promotes the application of advanced medical technology
2. Maintaining the validity of Market Authorizations (MAs) which expired from 01 July 2020 until these products are reviewed and are granted five-year MAs
3. Continuing to allow foreign medical practitioners (FMPs) to use interpreters when providing care for Vietnamese patients instead of enforcing Vietnamese language proficiency in the new Law on Medical Examination and Treatment

VIETNAM'S HEALTHCARE LANDSCAPE

Surge in demand for both quantity and quality of healthcare services



Vietnam's healthcare system has developed significantly over the past 20 years and continues to strengthen and make a positive impact on the health and well-being of Vietnam's population. As Vietnam has achieved remarkable economic growth, demand for better quality healthcare services has correspondingly increased, shaped by a shifting demographic, epidemiological, and socioeconomic landscape. Increasing average life expectancy and declining birth rates has resulted in Vietnam becoming one of the fastest aging countries in Asia. The growing population of elderly, coupled with the epidemiologic transition to chronic non-communicable diseases, has contributed to higher demand for comprehensive and long-term service provision. Additionally, people in Vietnam are becoming more proactive in seeking and investing in preventative health and well-being due to improved health information access and knowledge of treatment and prevention, as well as rising living standards and income levels.



Demographic, epidemiological, and socio-economic shifts contribute to rising healthcare demand in Vietnam



**75.3
years**

Life expectancy of Vietnam's population in 2018 - an increase of 15 years over the past 50 years



**7.2%
population**

Proportion of people aged 65 years and older in 2018 leading to high demand for care



**77%
total death**

Caused by non-communicable diseases (NCDs) – increasing mortality and morbidity burden of NCDs



**US\$
2,502**

Annual income per capita – grew at 8.6% per year over 2015-2018



**26% of the
population**

Proportion of the population expected to reach middle class by 2026 according to the World Bank



**35.9%
population**

Urbanization rate – forecasted by the Vietnamese government to reach 50% by 2030

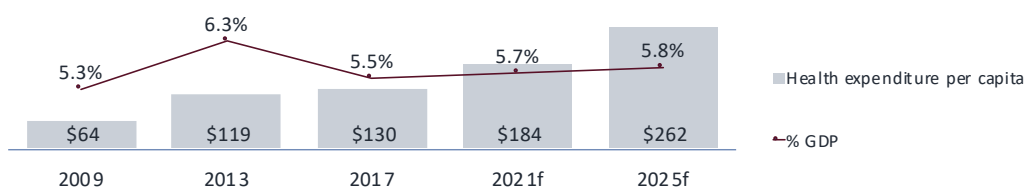


The public-dominated health system in Vietnam

Rising Healthcare Expenditure

Healthcare expenditure per capita is expected to grow at 9.2% per year over the 2009-2025 period, reaching \$262 by 2025. In recent years, Vietnam has had second highest total healthcare expenditure as a percentage of GDP in Southeast Asia, behind Cambodia.

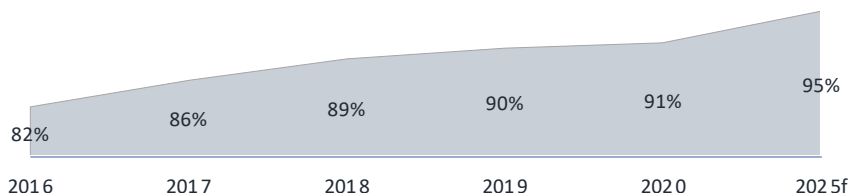
Health expenditure per capita and total healthcare expenditure as percentage of GDP 2009-2025f



National Health Insurance

Since its introduction in 1992, the National Health Insurance system has steadily expanded and provided affordable access to basic healthcare services to the population. The government is committed to achieve universal health coverage as part of an ongoing national strategy, aiming to reach 95% enrollment by 2025.

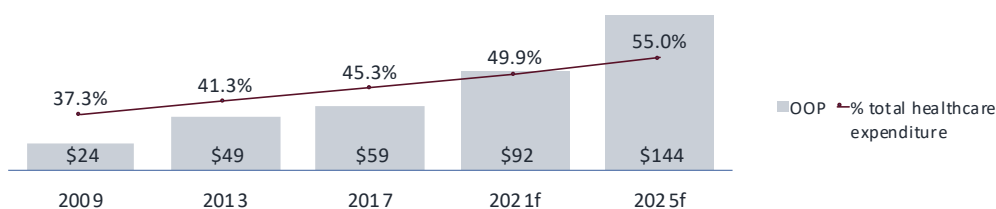
National Health Insurance Coverage 2016-2025f



High Out-of-Pocket (OOP) Payment

Vietnam faces high OOP payment, accounting for 45% of total health expenditures, impacting access to healthcare. OOP payments increased by 12% per year over the 2009-2017 period and are forecasted to maintain the same growth rate through 2025.

Out-of-pocket payment in numbers and as percentage of total healthcare expenditure 2009-2025f



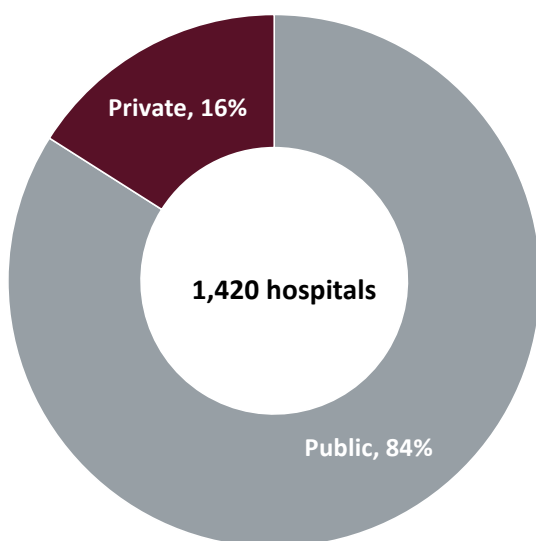
An Overview of Vietnam's Healthcare Sector

Rising healthcare demand poses a financial and capacity challenge to Vietnam's public sector-led healthcare system. Public hospitals account for 84% of the total number of hospitals in Vietnam and are categorized into 4 administrative levels: central level, provincial level, district level, and medical stations. In order to qualify for full reimbursement, patients need to follow a referral system from the local level up to the central level, but in many cases, patients tend to bypass the system by directly visiting central hospitals in major cities.

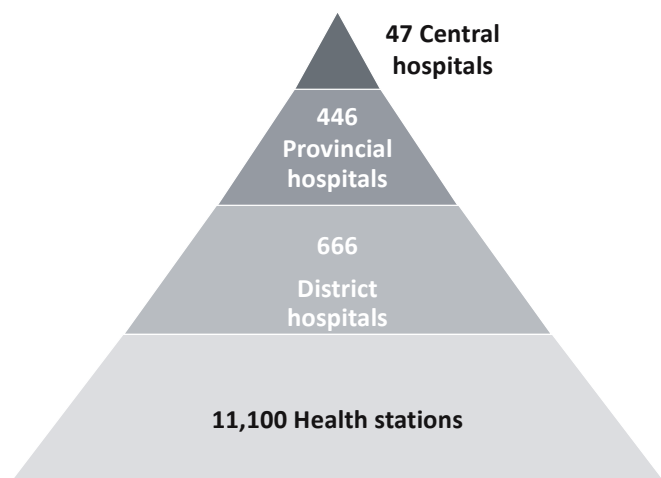


As a result, large public hospitals, such as Bach Mai Hospital (Hanoi) or Cho Ray Hospital (Ho Chi Minh City), face high inflows of patients, putting a strain on hospital capacity, resulting in high bed occupancy rates of 120-160%. Furthermore, with the transition towards independent hospital management starting in 2002 (Decree 10), public hospitals have taken on varying degrees of autonomy in terms of finance, personnel, and the organization and management of services. Many major public facilities are struggling to balance their own finances while trying to maintain high quality service as they classically were dependent on funding from the state.

The public-dominated health system in Vietnam



The 4 administrative levels of the public hospital system



**These are additional 33 public hospitals under the management of other Ministries.*

The Capability and Financial Constraints Facing Vietnam's Public Healthcare Sector



Insufficient hospital beds (<28 beds per 10,000) below WHO's recommendations of 50 beds per 10,000



Low doctor per capita ratio, at 8.6 doctors per 10,000 people in 2018



Strained and understaffed central & provincial hospitals, as patients demonstrate a preference to directly visit these facilities



Financial pressure of becoming less dependent on the state budget and covering their own costs following hospital autonomy policies initiated in 2002





The Development of Vietnam's Private Healthcare Sector

The development of Vietnam's private healthcare sector dates back to the early 1990s. Prior to 1989, healthcare services were provided free-of-charge to the population. To alleviate the burden on the state budget, the government introduced a series of policies to mobilize resources and reform healthcare financing and provision. One of the key elements of these reforms included the initiation of partial household out-of-pocket payments (Decision 45/HDBT) and the permission to operate private healthcare providers (Decision 94/BYT/QĐ). Since its legalization, the private healthcare sector has contributed to the delivery of healthcare services for both locals and foreigners living in Vietnam, encompassing a range of industry players, including medical devices, hospitals & clinics, pharmaceuticals, pharmacies, health insurance, laboratory diagnostics, and supporting industries.



Medical Devices



The high demand for better healthcare services is the key driver for investment in infrastructure and technology, including medical devices, at public and private healthcare facilities. The medical device market was valued at \$1.4 billion USD in 2019, making Vietnam the 9th largest market for medical devices in the Asia-Pacific region. The sector grew at a rate of 10.6% per year over the 2013-2018 period and is forecast to continue growing at 10.2% every year over the next 5 years due to expansion of hospital chains, adoption of international quality standards, and rising private healthcare investment. Efforts from Vietnam's government to strengthen the regulatory framework for management of medical devices as well as moving towards synchronization of quality with ASEAN standards and international norms also support the positive outlook of the medical device sector. In 2018, Decree No. 169 was issued to amend existing regulations (Decree No.36) on medical device management, creating favorable conditions to support both local and foreign manufacturing, and improving business conditions and administrative procedures for producers in line with Resolution No. 01/NQ-CP.

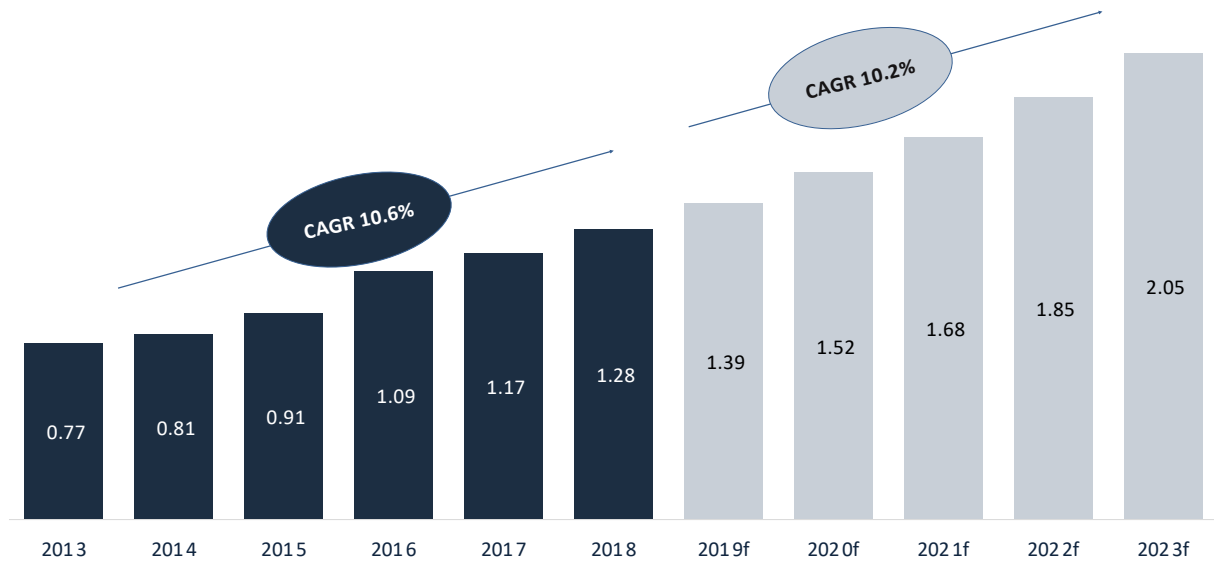
Medical devices report: Includes five-year forecasts to 2023, Fitch Solutions, Q3/2019

Vietnam imports large volume of medical equipment, The Saigon Times, Jul 26, 2018, link.

Government Decree No. 169/2018/ND-CP on Amendments to the Decree No. 36/2016/ND-CP on Medical device management

Government Resolution No. 01/NQ-CP on Key socio-economic development plan

The Fast-Growing Medical Device Sector in Vietnam (in \$ billion USD)



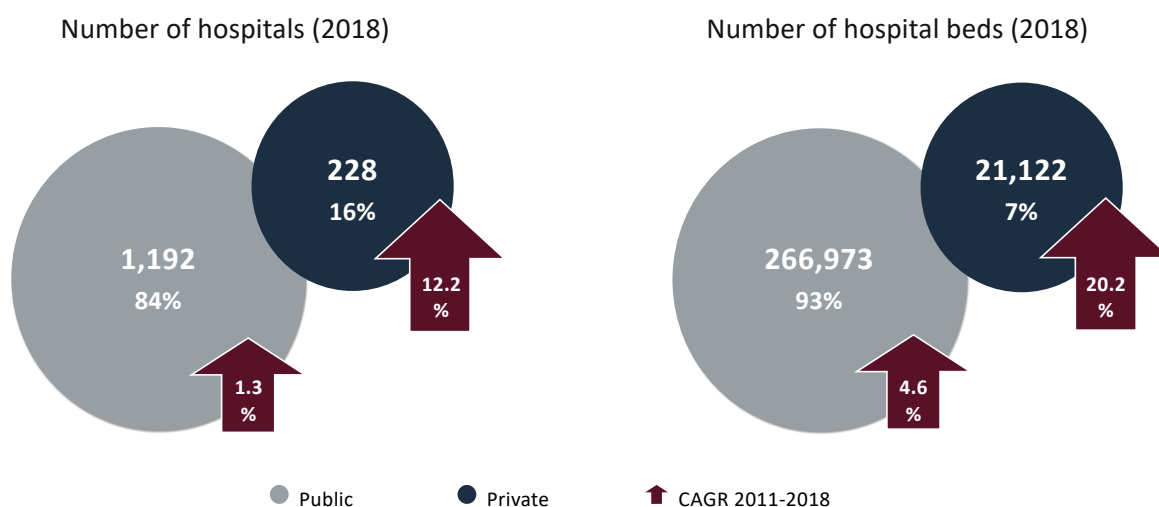
Vietnam has limited technical and technological capability for advanced medical device and equipment production with the market relying heavily on foreign investors to import and distribute technology. More than 90% of Vietnam's medical devices are imported. The U.S., Japan, Germany, China, and Singapore are the largest suppliers of medical devices, account for 55% of such imports. The most common imported medical devices and equipment include diagnostic imaging equipment such as X-ray, ultrasound, magnetic resonance imaging and computed tomography scanners, and equipment used for surgery, endoscopy, sterilization, testing and medical waste treatment. A total of 50 domestic manufacturers licensed by the Ministry of Health own ~10% of the market share and currently supply basic low value-added medical devices and equipment, such as hospital beds and consumables. In the near- and medium-term, these local manufacturers are unlikely to develop sufficient capability for production of advanced laboratory and clinical equipment to meet the rising demand, so the market is expected to continue its reliance on imported products.



Hospitals and clinics

As of 2018, there were 228 private hospitals in Vietnam, accounting for 16% of the total number of hospitals, but only 7% of the total number of hospital beds. Approximately 40% of private hospitals are in large cities, such as Hanoi and Ho Chi Minh City, concentrated to target upper-middle to high-income families willing to pay a premium.

The public-private mix of healthcare providers in Vietnam



Large private hospital chains from Thailand, Indonesia, Malaysia, Japan, South Korea, Singapore, the United Kingdom, and the United States have expressed interest in investing in private hospitals and clinics in Vietnam. From 2011-2018, the number of private hospitals in Vietnam grew significantly. AVHC members, such as the American Chiropractic Clinics, Victoria Healthcare, City International Hospital, American Eye Center, Raffles-SOS International Clinics, Gia An Hospital, and Franco-Vietnamese Hospital; other noteworthy private hospitals, such as Hoan My Hospital and Vinmec Hospital; and numerous small have been active during this period.



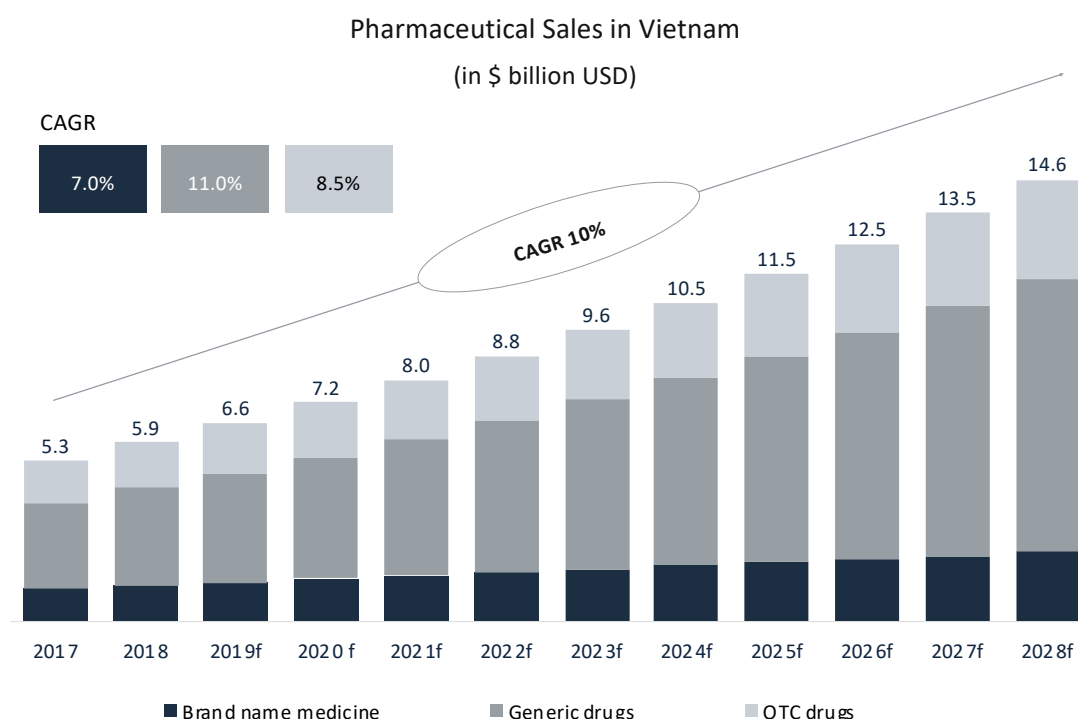
One of the critical factors fostering the development of private hospitals and clinics is the extensive financial and policy support from the government in creating a positive business environment for private investors. The commitments of Vietnam to the World Trade Organization include the permission for foreign healthcare service suppliers to provide services through 100% foreign-invested hospitals, joint ventures with local partners, or through a business cooperation contract. The minimum investment capital requirement for healthcare services is \$20 million USD for a hospital, \$2 million USD for a polyclinic unit, and \$200,000 USD for a specialty unit. The government also encourages the development of healthcare infrastructure through public-private partnership (PPP) investments. As of 2019, more than \$139 million USD have been raised in PPP projects between state-owned and privately-run hospitals. Opportunities for PPP healthcare projects hold a promising outlook, with the recent revision and adoption of the new Law on PPP investments (Decree No.63/2018/ND-CP) on June 18, 2020. The new Law on PPP investments incorporates amendments and refines the existing regulatory framework to facilitate PPP projects. Tax incentives are also used to encourage growth in healthcare enterprises with those satisfying specified conditions* being eligible for a preferential 10% corporate income tax rate for their entire operational period (instead of the 20% standard rate) and 4 years of overall tax exemption in addition to a subsequent 5 to 9 years of 50% reduction on the preferential corporate income tax rate (applicable to investments in specified locations).

The healthcare provider landscape in Vietnam is expected to become more dynamic, as Vietnam attracts more investments into the private sector. The increasing participation of private hospitals and clinics will benefit Vietnam's healthcare system in coping with surging healthcare demand and contribute to advancing overall quality standards for hospitals and clinics in the long-term.

*Conditions differ for each type of healthcare establishment (such as pharmacy, preventative medicine, hospital, etc.) and relate to factors such as location (such as in an area with difficult socio-economic conditions), number of beds, equipment, personnel, etc. Specific requirements are provided in the Decision No. 1466/QĐ-TTg dated October 10, 2008 (which was amended and supplemented by Decision no. 1470/QĐ-TTg dated July 22, 2016)

Innovative Pharmaceuticals

Vietnam's pharmaceutical market has undergone robust growth over the past decade. The pharmaceutical market was valued at approximately \$6.6 billion USD in 2019 and forecasted to grow 10% per year from 2017-2028. Pharmaceuticals make up a considerable proportion of healthcare expenditure, estimated at 38.1% of total healthcare spending in 2019. Pharmaceutical sales per capita is forecasted to nearly triple from 2017 to 2027, from \$55.4 USD in 2017 to \$131 USD in 2027. The rapidly expanding demand for pharmaceuticals is mainly driven by improved healthcare service accessibility, wider universal healthcare coverage, rising personal incomes, and better health awareness and management.



Branded medications in Vietnam have low market share with limited growth in both hospital and retail channels and contribute to only 20% of total pharmaceutical sales. Alternatively, generic drugs currently account for more than half of total sales. Sales of brand-name drugs are projected to have a 10-year growth rate of 7% while generic drugs are expected to grow 11% and OTC drugs at 8.5% in the same period.

Vietnam Pharmaceuticals & Healthcare Report - Includes 10-year forecasts to 2027, Fitch Solutions, Q1/2019

Government Circular No.34/2013/TT-BCT on Roadmaps for goods trading and directly related activities of foreign-invested enterprises in Vietnam

Government Decree No. 54/2017/ND-CP on Guidelines for implementation of the Law on Pharmacy

Government Decree No.155/2018/ND-CP on Amendments to some articles related to business conditions under state management of the Ministry of Health



Vietnam is one of the lowest producers of pharmaceutical products in terms of both market volume (4% of total market volume) and value (25% of total pharmaceutical value) in the APAC market. The pervasiveness of counterfeit brand-name pharmaceutical products on the market considerably affects sales despite government efforts to tighten legislation and impose severe penalties on violators who illegally produce and distribute counterfeit medical products.

Vietnam has not opened its pharmaceutical market to foreign investors to distribute drugs to end-customers on a wholesale or retail basis as it is subject to stringent regulations. According to Circular 34/2013/TT-BCT, a foreign invested enterprise is not permitted to distribute pharmaceuticals, and a wholly foreign-owned company can only import and export pharmaceutical products into Vietnam and sell their imported products to licensed local distributors, as stated in Decree 54/2017/ND-CP. Decree No.155/2018/ND-CP, a recent change to the Law on Pharmacy, granted permission to establish foreign investment enterprises (FIEs) allowing foreign companies currently operating representative offices to establish FIEs which are more stable and sustainable legal entities with broader scope of activities. FIEs can apply for the issuance of the Certificate of Satisfaction of Conditions, giving them the right to directly import and sell products to local wholesalers.

Vietnam has a unique and timely opportunity, through the development of the new National Strategy by the Drug Administration of Vietnam, to build a favorable environment with attractive incentives, in order to become the destination of choice in ASEAN for further investment and long-term commitments from innovative pharmaceutical companies.

Retail Pharmacies

The retail pharmacy sector in Vietnam has undergone significant development in terms of accessibility and quality improvement over the past decade. The market is shifting from the model of traditional independent pharmacies to modern pharmacy chains which benefit consumers, in terms of accessibility, product and service diversity, and quality consistency. Currently capturing just 3% of the market, modern pharmacy chains are gaining traction with consumers and are attracting private investment from both domestic and foreign players.



Market competition has become increasingly intense with the rapid expansion of modern pharmacy chains, such as Pharmacy, Long Chau, Medicare, Phuc An Khang, and others, competing for brand positioning and market share. In the first quarter of 2020, Pharmacy (an AVHC member) – the largest modern pharmacy chain in Vietnam – opened 51 new stores.



A key factor leading to the growth of modern pharmacy chains is the efforts from the government to improve drug distribution quality in recent years in order to tackle major problems such as counterfeit drugs and antibiotic abuse. Besides mandatory business license requirements (namely the Certificate of Eligibility for Pharmaceutical Business), the government has implemented the Standards of Good Pharmacy Practice (GPP) applicable to all pharmacies operating in Vietnam since 2007. To qualify for and maintain the GPP Certificate, the drug retail establishment must comply with infrastructure, technical, and personnel requirements as specified in the current regulations. The licensed pharmacist managing a pharmacy is required to obtain a Pharmaceutical Practice Certificate (PPC), which includes both professional certification and a training period for certain skills. The GPP Certificate is normally reassessed by the Ministry of Health every three years. In addition, the government has implemented a national digital platform to strengthen managing, monitoring, and supervising sales activities for all pharmacies in Vietnam. All pharmacies in Vietnam are required to integrate into the national pharmacy network. In 2019, about 15,178 pharmacies (accounting for 80% of total pharmacies) have successfully connected to the national portal. The coverage is expected to increase to 100% by end of 2020.

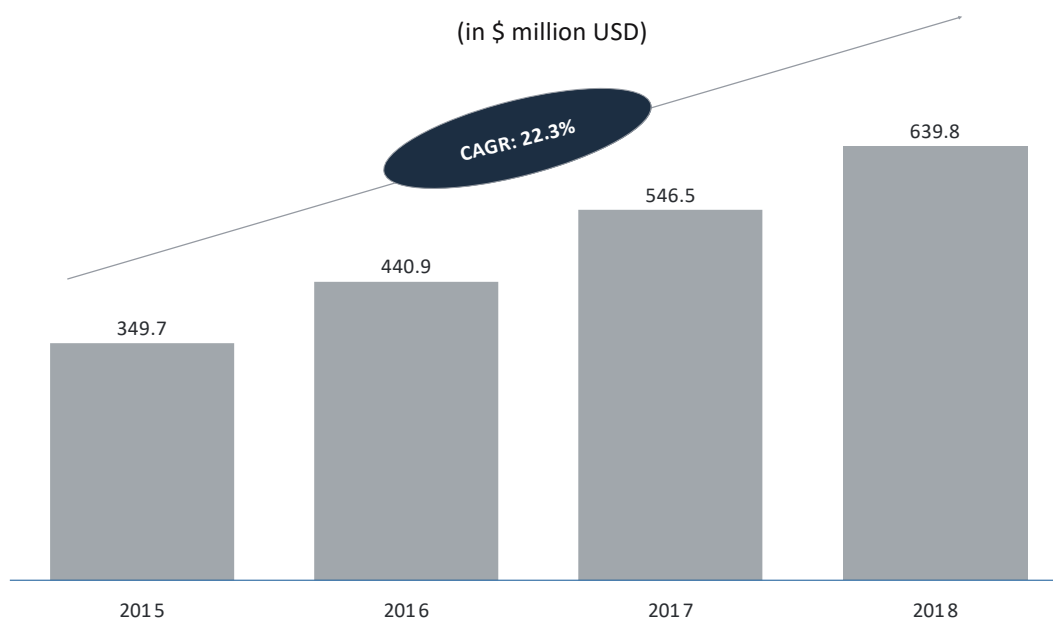


In alignment with the government in tightening regulations for drug distribution activities, modern pharmacy retailers offer unique value in consistently improving quality and safety of drug distribution. The fast-growing modern pharmacy networks will continue attracting new investors and increasing competition intensity, encouraging players to continually strengthen their product and service offerings while putting consumer interests first. As a result, consumers will gain the benefits of easy access to pharmacies throughout Vietnam with the assurance of purchasing legitimate products, receiving high-quality service from well-trained pharmacists, and competitive market prices.

Private Insurance

Vietnam's government implemented a National Health Insurance program in 1992 to make healthcare services more affordable for the population. The government is committed to achieving universal public health insurance coverage with 90% of the population estimated to be covered in 2019 and a goal of 95% enrollment by 2025. Under the program, the government covers 80%-100% of basic medical examination and treatment fees. However, high out-of-pocket payments account for about 45% of health expenditures and are expected to grow at 12% per year through 2020. As the financial burdens of healthcare expenses mount on Vietnamese families, consumers are turning to insurance in order to ensure their access to healthcare and are enrolling in private health insurance plans to supplement their public insurance in increasing numbers.

Private Health Insurance Market Size in Vietnam, by Gross Insurance Premium



In 2018, the private health insurance market size was valued at \$639.8 million USD by the value of gross insurance premiums. Higher incomes, increasing health awareness, and improved consumer knowledge of insurance products are key growth drivers leading the private health insurance sector in Vietnam to grow 22.3% from 2015-2018. The increasing number of consumers purchasing health insurance products view spending on health insurance products as a long-term health investment and a method to mitigate physical and financial risks related to health.



The non-life insurance segment, with healthcare as one of the primary sub-segments, is largely contributed by local companies representing approximately 70% of the market. The remaining 30% of market share is comprised of foreign insurers, such as Aetna (AVHC member), Liberty Insurance, AIA, and others. Both foreign and local insurers offer a wider range of medical services including those not covered under public health insurance, allowing patients to choose the most appropriate insurance products to suit their needs.

Though the private health insurance market enjoys strong growth, the current penetration of private health insurance remains low in Vietnam, suggesting that there is room for further growth for private health insurance providers in the long-term in order to help reduce the financial burden on Vietnamese consumers accessing healthcare services.

Laboratory Diagnostics

The laboratory diagnostics sector plays a critical role in Vietnam's healthcare delivery system, making a direct impact on medical decisions and patient clinical outcomes. The laboratory diagnostics market in Vietnam has a market value of less than \$1 billion USD. However, clinical lab tests are projected to rise in volume in the upcoming years attributable to several factors, including: government efforts to increase public health insurance coverage to 95% of the population by 2025, scheduled upgrades at diagnostic lab facilities at large public hospitals, and independent private labs expanding across Tier I cities to increase their reach and offer more testing options to customers.

Clinical testing in Vietnam is generally divided into two segments: public hospital labs and private independent labs. Most laboratory services are provided in the public hospital system, accounting for 75% of the market value. Private independent laboratories have recently grown rapidly, currently representing 25% of the market and projected to grow 10-15% per year.

Private independent labs, including Diag (AVHC member), Medic Lab, and Labcare Diagnostics Center, with their ability to receive foreign investments are positioned to increase diagnostics and testing capacity and capability, catering to the ever-growing demand from NCD-related tests and during times of crisis, such as the COVID-19 epidemic.



Medical Diag Centre's internal reports



AMCHAM VIETNAM, HO CHI MINH CITY AND DA NANG HEALTHCARE COMMITTEE MEMBERS IMPACT ON VIETNAM

Committed to achieving the aspirations set forth in AVHC's vision and mission statement, our members have actively contributed to the development of healthcare in Vietnam, creating positive outcomes for the health and well-being of Vietnamese people by enhancing both quality and accessibility to healthcare and by giving back to the community as corporate social responsibility stewards. AVHC member companies have been particularly active in:

- 1) Increasing access to healthcare services, and
- 2) Enhancing quality of healthcare services in alignment with international standards.



Increasing Access to Healthcare

AVHC members have invested in healthcare facilities and infrastructure across the healthcare landscape, from private hospitals and clinics, diagnostic labs, and pharmacy retailers to medical devices and equipment. The availability of AVHC members' healthcare services provide Vietnamese nationals and foreigners living in Vietnam with a wide range of services to choose from, serving a diverse set of needs and increasing local access to healthcare.

In addition, the investment of AVHC members into healthcare aligns with initiatives from the Vietnamese government to promote and strengthen the provision of private healthcare, aimed at alleviating the capacity constraints facing the public system.



Numerous AVHC members' investment activities to improve access to healthcare include:

- The Medical Devices Subcommittee members (including B Braun, Diversatek, Medtronic, and Terumo) have invested in the production of medical devices, supplies, and components in Vietnam, including high-end GI diagnostics; OEM capital equipment; blood bags; printed circuit boards and molded plastic components for medical devices; and high quality consumables used worldwide in hospitals and clinics.
- Members of the Healthcare Providers Subcommittee (including Victoria Healthcare International Clinics, Franco-Vietnamese Hospital, City International Hospital, Gia An 115 Hospital, American Chiropractic Clinic, and American Eye Center) have opened clinics and hospitals following international standards serving both local and foreign communities.
- Pharmacy, a modern pharmacy chain, is growing rapidly with +396 outlets located in various provinces in urban and rural areas acting as accessible frontline healthcare for patients to purchase quality medicines (especially over-the-counter medicines), to receive services from well-trained pharmacists, and to obtain reliable health information.
- The Medical Diag Center has opened laboratory and medical diagnostics centers with advanced equipment and technology offering convenience for patients and enhancing access to modern laboratory testing services. These labs also provide supplementary support to small-sized private clinics which currently have limited laboratory infrastructure. Diag test results assist doctors at small clinics to improve service to patients helping relieve overcapacity issues at public facilities.





Promoting Quality of Healthcare Services in Alignment with International Standards

AVHC members play a critical role in showcasing and promoting the adoption of international standards and best practices improving the quality of healthcare services and patient outcomes for the entire industry. AVHC members are active in supporting Vietnam's government through both normal business operations and CSR efforts to address existing challenges, such as increasing antibiotic resistance, counterfeit and illegally-imported drugs, rising burden of non-communicable diseases, and preventative medicine practices.



Implementation of international best practices fosters technical skills and technology transfer and is not limited to information sharing within the healthcare provider community or best practices at pharmacy retailers and diagnostic laboratories for consistently high-quality services. It is also applicable to the research and development and technology transfer in pharmaceutical, medical device, and equipment manufacturing. As a result, the healthcare system in Vietnam will continue to develop to gain competitive advantage within Southeast Asia.

Another by-product of high-quality healthcare service is the additional revenue inflow from medical tourism to Vietnam. Private hospitals and clinics introduce healthcare services at international standards (such as adoption of the Joint Commission International standards) which help attract inbound medical tourists to Vietnam, significantly contributing to Vietnam's economy. More than 300,000 foreigners were treated in hospitals in Vietnam in 2018, with most foreign patients being overseas Vietnamese, Cambodians, and Laotians.

AVHC members have enhanced the quality of healthcare services through:

- Members of the Medical Devices Subcommittee set high standards for manufacturing technologies, and while some AmCham Vietnam, HCMC and Da Nang member companies are producing and selling medical equipment through distributors in Vietnam, most companies are primarily importing products into Vietnam.
- Foreign and foreign-trained healthcare professionals working at private hospitals and clinics promote knowledge and skills sharing within the healthcare professional community.
- MSD has implemented the Anti-Microbial Stewardship program at 17 key hospitals nationwide to mitigate antibiotic resistance. MSD Mothers program, part of the MSD for Mothers Global Giving Program, awarded a grant of \$1.25 million USD over three years to Population Services International to improve women's health in Vietnam. UNFPA-MSD Technical Collaboration launched an HPV vaccination program in Vietnam.
- Pharmacy ensures that all its pharmacies comply with the Good Pharmacy Practice (GPP) quality standards regulated by the government so that consumers can purchase products knowing that they are authentically sourced, licensed, stored, and dispensed per government standards and that pharmacists are professionally trained to consult with frontline medical advice.
- International private insurers (including Aetna International in partnership with Bao Viet GE, AIG, Prudential, Manulife, and Chubb) and international auxiliary service organizations (such as Aon, Willis Tower Watson, Marsh, and Aegis), provide insurance premium revenues to the economy; bring regional expertise in international best practices; introduce new products and services to the market; and help optimize the regulatory landscape for insurers in Vietnam to maintain their competitiveness in the region through policy advocacy, while AVHC members have helped attract investments and new insurance fields, such as insurtech, in to the market.
- Laboratory and imaging diagnostics provide vital information to doctors to allow faster decision making and improve patient outcomes – early diagnosis of disease and discovery of chronic health issues enables early intervention, better prognosis, and lower overall spending due to the avoidance of advanced treatments, surgeries, specialized pharmaceuticals, and other expensive treatments.





KEY ADVOCACY ISSUES BY AMCHAM
VIETNAM, HO CHI MINH CITY AND DA
NANG HEALTHCARE SUB-
COMMITTEES

MEDICAL DEVICES

Summary of Recommendations

- I. Ensure that the new Law on Medical Devices Management meets the needs of Vietnam's healthcare system and its supporting industries
- II. Streamline the registration process of medical devices for use in Vietnam and harmonize the approach with ASEAN standards
- III. Provide clear and consistent guidance to companies and providers on the placement and rental model for medical equipment and devices in public hospitals

Advocacy Issues

- I. **Vietnam's existing legal framework does not yet have specialized legislation for medical devices and equipment.**

Issue Description

There are thousands of types of medical equipment and devices, ranging from simple products, such as cotton bandages, to highly complex technology, such as magnetic resonance imaging (MRI), computed tomography (CT) scanners, and radiotherapy linear accelerators. Many are complex products that undergo regular adjustment and innovation to ensure they meet the evolving requirements of healthcare service providers. However, the existing legal framework in Vietnam does not have specific legislation for medical devices and equipment and has been previously based on provisions found in other general laws (including the Law on Commerce and the Law on Product and Goods Quality).

To address this gap, and at the request of the Communist Party of Vietnam, the government is proposing the development of a Law on Medical Devices Management.

"Several solutions to strengthen state management of medical equipment and devices," Ministry of Health, October 04, 2014, link.

Central Party Resolution No. 20/2017NQ-TW dated 25/10/2017.

Government Resolution No. 139/2017/NQ-CP dated 31/12/2017.

Central Party Resolution No. 20/2017NQ-TW dated 25/10/2017.

Government Resolution No. 139/2017/NQ-CP dated 31/12/2017.



The proposed law is currently scheduled to be submitted to the National Assembly within 2020. The Law will systematize scattered regulations and address limitations in existing Decree No. 36 and Decree No. 169, including:

- Standards for imported medical devices and equipment: Despite reliance on imported medical equipment, there is no specific standards for these items; instead, compliance depends the Law on Commerce and Decree No. 187/2013/ND-CP.
- Support to domestic production of medical devices: Existing regulations have not effectively supported domestic production.
- Quality of medical equipment and devices: Currently, product quality is regulated by the Law on Product and Goods Quality (Article 5) and by respective national standards (as stipulated in Article 3 of the Decree No. 132/2008/ND-CP).
- Progress toward harmonization with ASEAN regulations on medical equipment and devices: There is currently no law-level basis to support Vietnam's institutionalization of the ASEAN integration roadmap on medical equipment and devices (ASEAN Medical Devices Directives).

Recommendations

As the government develops this new Law on Medical Devices Management, the Medical Devices and Equipment Subcommittee recommends that:

1. The government actively consult industry stakeholders and request their support to the drafting committee of the Law. Industry stakeholders can assist the committee in understanding and resolving challenges facing the industry in order to create a hospitable and thriving medical device sector in Vietnam;
2. The Law explicitly supports improvements to the processes of regulatory agencies for medical devices and equipment management to ensure they are in harmony with international standards in order to ensure competitive and transparent procurement of medical devices and equipment;
3. The Law promotes the application of advanced medical devices and equipment, and associated knowledge transfer, which will form a strong foundation for deepening the skills of the healthcare sector's labor force.

II. Vietnam's medical equipment registration and licensing procedures are lengthy and convoluted, resulting in delays and many backlogged dossiers awaiting the Ministry of Health's approval.

Issue Description

In 2019, the Ministry of Health had to review, appraise, and approve more than 8,000 registration dossiers for medical devices and equipment submitted under Decree No. 36/2016/ND-CP. The number of dossiers to be appraised and approved by the Ministry of Health will likely be higher in 2020 and beyond as the healthcare sector keeps expanding. However, the online registration system is not fully complete, causing delays and difficulties in guiding the industry and appraising the circulation application dossiers for type B, C, and D medical devices.

Additionally, the number of assigned staff to manage the circulation registration of medical devices and equipment is limited. In order to process the application in a timely manner and in harmonization with the ASEAN Medical Devices Directives, there is an urgent need for human resources (basic, advanced, and specially trained) to review and appraise the registrations of medical device circulation as well as inspect and monitor the medical device sector.

In 2018, the government released Decree No. 169/2018/ND-CP to supplement Decree No. 36/2016/ND-CP on the management of medical equipment and devices, aiming to reform some management principles to improve efficiency, overcome challenges, and gear the medical device sector towards regional standards (the ASEAN Medical Devices Directives). However, Decree No. 169/2018/ND-CP does not cover regulations on adjustments currently practiced by the industry, resulting in challenges for businesses given the specific nature of medical equipment and devices constantly requiring innovation for better performance. This was an impediment to the industry and went against international and regional standards.

Recommendations

As the government develops this new Law, the Medical Devices and Equipment Subcommittee recommends that:



1. Optimization of the online circulation registration system to enable timely compliance and support efficient appraisals and approvals;
2. Extension of the registration timeline for medical devices until at least early 2022 as per the current draft Decree (“new draft Decree”);
3. Acceleration of Vietnam’s effort to harmonize with the ASEAN Medical Devices Directives and the Common Submission Dossiers Template, with an appropriate extension to early 2021, at the earliest, given the new draft Decree;
4. Finalization of a separate mechanism for medical devices already in use to reduce the level of application appraisals while maintaining high standards.

III. There is limited guidance on the implementation of the placement and rental model for medical equipment and devices in public hospitals.

Issue Description

Decree 151/2017/NĐ-CP dated 26/12/2017 allows hospitals to purchase or rent medical devices. Prior to the implementation of this Decree, public hospitals used placement model to improve patient access due to limited government’s budget. There is currently limited guidance on the implementation of the rental model, and there is a risk of no reimbursement or inconsistent payments which conflicts with Decree 151.

Recommendations

The Medical Devices and Equipment Subcommittee proposes that the Ministry of Health, the Vietnam Social Health Insurance Department, and the Ministry of Finance align and develop a detailed guidance for the placement and rental of medical equipment and devices in public hospitals. The Subcommittee suggests that the placement model be used as an interim solution while waiting for the drafting of the regulatory guidance, and the Vietnam Social Health Insurance Department continues to pay for consumables used in the placement model until the rental model guidance is available.

HEALTHCARE PROVIDERS

Summary of Recommendation

Continuing to allow foreign medical practitioners (FMPs) to use interpreters when providing care for Vietnamese patients instead of enforcing Vietnamese language proficiency in the new Law on Medical Examination and Treatment

Advocacy Issues

The new draft Law on Medical Examination and Treatment will help Vietnam to advance its healthcare system, with the private sector working alongside the public sector to serve the Vietnamese people. The current system of using qualified medical translators has functioned well and has allowed the Vietnamese people a wider choice of healthcare providers. It will also be needed to serve foreign patients as medical tourism develops. Requiring FMPs to have Vietnamese language proficiency in order to conduct medical examinations and to provide treatment to Vietnamese patients will potentially create some short-term and long-term problems for both Vietnamese and foreign patients and would contribute to the overloading of Vietnam's healthcare system.

Issue Description

The government of Vietnam has proposed a draft amendment to the Law on Medical Examination and Treatment ("Draft Law") which includes Vietnamese language proficiency as a mandatory requirement for FMPs to obtain license and to conduct medical examinations and provide treatment to Vietnamese patients.



We question if this requirement is in keeping with goals of the healthcare system, especially as medical tourism develops and as Vietnamese patients become more sophisticated and better able to make informed choices in their personal healthcare.

Unfortunately, the Draft Law does not permit a Vietnamese to choose an FMP who does not have “a good command of Vietnamese”. This can be considered as a form of discrimination and unfairly favors foreigners who remain free to choose. Many Vietnamese are now fluent in English, French, and other languages. English is officially required to be taught in Vietnamese schools. Many Vietnamese are comfortable discussing their health issues with FMPs in English. If not, experienced medical translators, mandated and certified since the Law on Medical Examination and Treatment of 2009, have worked extremely well. We believe that the requirement for FMPs to be proficient in Vietnamese to serve Vietnamese patients is essentially preventing Vietnamese patients from having a wider choice in their healthcare, considering there is already a solution for language barriers if it exists is negative for the development of the industry.

Since few FMPs have a good command of the Vietnamese language, experienced practitioners will be forced to leave Vietnam. Foreign operated hospitals will be severely affected. It will be unlikely that other FMPs will come to Vietnam with a restrictive language environment. This will have a dampening impact on foreign companies and their staff who may perceive Vietnam as less friendly to foreigners. It could discourage foreign investment in healthcare, since their overseas staff would be excluded. As outbound medical tourism is a major issue, this could become more severe.

The proposed Draft Law would turn away medically skilled FMPs who help to reduce the burden of the shortage of doctors. It can also hinder FMP specialists from abroad who can bring cutting edge technologies to Vietnam as the country strives to develop world-class care. As noted, it could also impede growth of medical tourism, as choices for the average medical tourist are restricted.

Recommendations

The AVHC recommends continuing the current system of skilled medical translators to assist in communicating between FMPs and Vietnamese patients, as it has been effective for the previous +10 years. Medical translators are widely used around the world, especially in countries which serve medical tourists. The broad international use of medical interpreters in many countries should give comfort to medical administrators in Vietnam that this piece of medical tourism is already in place. Clearly, countries which have focused on attracting inbound medical tourism can easily facilitate communications through interpreters. As new medical tourism destinations emerge (e.g., Malaysia) they foster an international image, which is much easier with an international array of doctors. Accredited interpreters are a common, professional solution, and a standard operating procedure in nearly all countries. It would be ironic if Vietnam can solve communications issues involving persons who travel to Vietnam for medical treatment but rejects the same solution for its own citizens.

We wish to help the government of Vietnam find ways to increase the number of physicians and utilize FMPs more broadly (e.g., pro bono care, teaching and training opportunities, expanding international cooperation and opportunities with foreign medical schools and teaching hospitals, exchange students/professors, etc.). Limiting their ability to treat Vietnamese patients works against the goals of the Ministry of Health to develop a world-class healthcare system and attract medical tourists.



INNOVATIVE PHARMACEUTICALS

Summary of Recommendations

- I. Maintain the validity of Market Authorizations (MAs) which expired from 01 July 2020 until these products are reviewed and are granted five-year MAs
- II. Ensuring harmonization of the Vietnam Certificate of Pharmaceutical Product (CPP) requirements with international guidelines and practice to ensure patients' earliest access to new medicines
- III. Adopt Intellectual Property protections that encourage U.S. pharmaceutical companies to invest in innovation in Vietnam

Advocacy Issues

- I. The delay of visa renewal approvals, while many Market Authorizations (MA) expired as of 01 July 2020, will directly impact the supply of medicines, particularly in light of the COVID-19 epidemic.

Issue Description

According to a preliminary survey from 1 July 2020 to 30 June 2021, there will be at least 730 pharmaceutical product MAs expired, including MAs of 669 drugs, 10 vaccines, and 51 biologics from leading multinational pharmaceutical companies from Europe, the United States, and Japan. Many of these medicines are for treatment of acute and chronic illnesses, some of which only have one registration number on the market and there is no alternative for continued patient treatment.

This figure will be significantly higher when all similar cases on the market are taken into account. After the issuance of Circular 32/2018/TT-BYT, companies have submitted a large number of dossiers.

Survey from 33 pharmaceutical companies with headquarters with Europe, the United States and Japan.

For five-year MA extension, companies must commit that products are manufactured and marketed exactly with the information approved by the Ministry of Health.

If there is any change to the product during the MA validity, companies must apply for approval of such change(s) following a different administrative process in Circular 32, and in line with ASEAN and ICTD.

In addition, the DAV is in the process of building an online database for all authorized medicines, which requires all five-year MA extension dossiers to be submitted in both paper and online format. This will reduce the administrative burden on the management of drugs circulating on the market for the DAV and relevant government agencies. Following global experience, we understand that the completion of this online database requires more time and resources.

During this period, we are very concerned and would like to alert the Vietnamese government about the potential risk that many MAs will expire prior to receiving their five-year extensions, which will result in shortages of both branded and generic medicines, impact patients currently being treated, and affect the entire healthcare.

In practice, multinational pharmaceutical companies need 3-6 months to plan, manufacture, and import medicines to Vietnam, after receiving MA approvals from the Ministry of Health. Therefore, the duration and continuity of MAs is crucial for companies to make appropriate and timely preparations. Especially, in the present context where the global supply chains are already stretched due to the complicated developments of COVID-19, the planning for Vietnamese market needs to be more thorough and urgent.

Following the Pharma Law, the MA extension process is a compulsory administrative requirement every five years. The quality, safety and efficacy of all products applying for MA extension remains exactly the same as current products on the market, as approved by the Ministry of Health. For this reason, many countries around the world, including those in the region such as Singapore, Thailand, and Malaysia, have put in place the mechanism of having just one Marketing Authorization number throughout the product life cycle, and only requiring MA maintenance fee, rather than MA extension application.



Recommendations

A large number of medicines are currently under the review process for MA extension. In order to avoid any impact on consequential interruption to the continued treatment of patients, and to reduce pressure on the healthcare sector during this critical period, as well as to facilitate companies' production planning, we would like to recommend the following practical approach: to maintain the validity of MAs which expire from 01 July 2020, until these products are granted five-year extension MAs.

Given the complications arising from the COVID-19 epidemic and to avoid a direct and immediate impact on the supply of medicines, we respectfully seek the urgent attention and direction from the Ministry of Health.

II. Circular 32 can potentially delay registration of new and already authorized imported pharmaceuticals, hindering patient access to new treatments, and adding an additional burden to the health system in Vietnam.

Issue Description

For foreign pharmaceutical products to obtain and maintain marketing authorization in Vietnam, companies must submit CPPs as part of the registration dossier to the Ministry of Health. These CPPs are issued by other health authorities in the world. In 2018, the Ministry of Health approved the Circular 32/2018/TT-BYT ("Circular 32") introducing new, very specific requirements on the CPPs of drugs and medicinal ingredients. In particular:

- The content of CPPs must include very specific information, such as specifications of finished product, specifications of all Active Pharmaceutical Ingredients ("API"), the names, addresses of all API manufacturers, that are not part of the format recommended by WHO and adopted by health authorities globally; and
- Drug Administration of Vietnam will contact CPP-issuing authorities to verify the authenticity of all CPPs.

Circular No. 32/2018/TT-BYT dated 12/11/2018.

Article 23.4.d, Government Circular No. 32/2018/TT-BYT dated 12/11/2018.

Article 12.1, Government Circular No. 32/2018/TT-BYT dated 12/11/2018.

Following Circular issuance, health authorities have provided feedback:

- None of the authorities can issue CPPs with all the information mandated by the government of Vietnam.
- Some authorities can verify the authenticity of CPPs submitted, upon request of the Ministry of Health.

The Subcommittee is therefore significantly concerned that the continuation of Circular 32, should it remain in force, will bring immediate and severe consequences:

- Impeding patient access to both new and previously authorized imported pharmaceuticals
 - New and innovative medicines which were ready to enter the Vietnamese market will now face the risk of being delayed or not accepted.
 - Medicines already authorized will be at risk of supply disruption and availability, as companies need to (re)submit CPPs to extend or renew products' MAs.
 - Donation programs from non-profit organizations and other agencies will face similar risks.
 - In 2020, at least 344 products will be impacted, amongst which are many life-saving medicines and will have a cumulative effect over time, as more medicines will be rejected and no longer available.
- Significantly burden the health system, and work against Vietnam's efforts to harmonize with international standards
 - As CPPs with existing format cannot be used, health authorities are expected to issue specific CPPs for the Vietnamese market. Even if this was feasible, at least 45 CPPs must be issued by the U.S. Food and Drug Administration to meet the Vietnam requirements in 2020 alone, significantly increasing the workload for other authorities and defeating the purpose of the WHO-CPP Scheme to support health authorities in optimizing resources and speeding up the MA granting process.

Recommendations

As the issue is becoming more urgent and impacting patient access, the Innovative Pharma Subcommittee is extremely concerned and seeks the continued attention and support of the government of Vietnam to address this issue, through:



1. Ensuring harmonization of Vietnam CPP requirements with international guidelines and practices (WHO-CPP Scheme), through revising relevant clauses in the Registration Circular, to remove additional information not specified in WHO-CPP format;
2. In the interim, towards the revision of the Registration Circular, propose to accept the submission of dossiers with CPPs under existing format as issued by health authorities.

III. Adopt Intellectual Property protections that encourage U.S. pharmaceutical companies to invest in innovation in Vietnam.

Issue Description

- Vietnam does not provide an effective patent enforcement mechanism, nor adjust the patent term to compensate for the unreasonable delays in granting Marketing Authorization or patent protection, thus eroding the effective term of patent protection available for innovative medicines.
- As part of the implementation of Vietnam's obligations under Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), the Circular 05/2010/TT-BYT on data protection provides, on paper, for five years of regulatory data protection (RDP). In practice, however, the practical enforcement of this protection has proved challenging.

Recommendations

The Innovative Pharma Subcommittee strongly recommends that:

The adoption of IP protections that conform to international obligations and standards – including meaningful RDP, clarification of the scope of patentable subject matter, and implementation of effective patent enforcement mechanisms – would greatly assist Vietnam in creating a more predictable environment for investment in innovation and enhance transparency and predictability.

RETAIL PHARMACY

Summary of Recommendations

- I. Endorsing and establishing regulations on online pharmacy sales to make medicines accessible for the elderly, bed-ridden patients, disabled, and rural patients via modern pharmacies
- II. Ensuring the implementation of appropriate measures to protect both patient information and business data of the hospitals, pharmacies, and patients before data transfer to the Vietnam Pharmaceutical Portal
- III. Allowing retail pharmacies to dispense medicines subsidized by Social Health Insurance to enhance patient access

Advocacy Issues

- I. **The development of regulations on e-prescription and online consultation will enable online medicines purchases to best service the underserved, elderly, bedridden, and disabled population while enabling modern healthcare to reach rural citizens**

Issue Description

Online pharmacy is a much-needed essential service to the population in an era where social distancing is required due to the COVID-19 epidemic and where the growing population of Vietnam is either aging or occupied at their workplaces unable to shop outside for pharmaceuticals. Furthermore, in our daily lives we often overlook the elderly, bedridden, and disabled that are relatively immobile and unable to purchase their medicines directly at a pharmacy or get direct healthcare access. Online pharmacies can help bridge the gap and bring pharmacy services directly to the underserved population.



Modern pharmacies with higher standards in healthcare operations and quality products are growing fast to service the people of Vietnam but are primarily limited to large cities or towns. The development of modern pharmacies on its own cannot fully reach rural areas. Therefore online pharmacy is the ideal solution to provide the underserved population access to quality healthcare while providing the government health agencies the data and compliance procedures to best comply with regulations. Modern pharmacies have capabilities of modern information systems to manage traceability of their medicines and products. This is ideal for compliance with growing concerns of government health agencies regarding dispensing and controlling of online medicine sales.

Recommendations

The Pharmacy Subcommittee recommends the establishment of a regulatory framework to promote online pharmacies to make medicines more accessible for the elderly, sick, and disabled population as well as people living in remote and rural areas. Online platforms are a potential solution healthcare, and the online pharmacies are suited to partner with government agencies to exploit their modern logistics systems and traceability.

II. The requirement of pharmacies to transfer the patient data, which are treated as “State secrets” and strictly protected by the law, to the Vietnam Pharmaceutical Portal raises concerns on potential conflicts with other Laws on Data Privacy Protection and Business Competition.

Issue Description

The Ministry of Health implemented Directive 23/CT-TTg (“Directive 23”) to strengthen the management of pharmaceutical distribution through the establishment of the Vietnam Pharmaceutical Portal (“VPP”), aiming to prevent the purchase and sale of counterfeit, substandard drugs, and to control antibiotic resistance in Vietnam. In addition, Decision 540/QĐ-QĐ of the Drug Administration of Vietnam (“Decision 540”) identifies information that will become part of the database of drugs consumed in the market. Decision 540 requires pharmacies to transfer three sets of data to VPP, including:

- Standard basic data (e.g.: drug name, retail price, registration number, name of active ingredient, strength of medicine, manufacturer, etc.) to local Departments of Health and the Ministry of Health;
- Standards for general output data (e.g.: drug name, retail price, registration number, name of active ingredient, strength of medicine, manufacturer, etc.) on the drugs sold within a specific province or city; and
- Standards for output data of the prescribed drugs (e.g.: name of hospital, name of patient, patient code, disease code, name of prescribed drugs, etc.).

The Retail Pharmacy Subcommittee has the following concerns regarding the Decision 540:

- Firstly, our concern revolves around the fact that pharmaceutical businesses, hospitals, and clinics, including doctors and medical practitioners, are responsible strictly to protect the data of their patients. Both the Law on Medical Examination and Treatment (“LMET”) and Circular 67/2015/TT-BCA of the Ministry of Public Security (“Circular 67”) list medical records as state secrets. Particularly, the Appendix I-1a of Circular 02/2018/TT-BYT of the Ministry of Health at Section III.4.a defines that every pharmacist who works at a pharmacy must “keep information concerning the patient’s illness and relevant information confidential”. In addition, personal information of the patient must be protected in accordance with Section 2, Chapter II of the Law on Network Information Security. The data which must be provided under Decision 540 includes both personal information of the patient as well as parts of the medical record of the patient. Our members are subject to the laws which protect private medical information. The operators and managers, pharmacies, hospitals and/or clinics and VPP will face sanctions and administrative and criminal penalties if such information is released or inadvertently misused in conflict with any other Law that may apply.
- Secondly, we are concerned that once private medical and related information is available to VPP and without appropriate protection, it may be passed on and shared in the market without regard to these important privacy requirements. Our members are also very concerned about sensitive business data of hospitals, manufacturers, pharmacies, and operators. If this information is misused by competitors, it is likely that relevant provisions of the Competition Law will be breached, resulting in an unnecessary and costly use of resources to enforce such provisions. Furthermore, pursuant to article 4 of the Law on Intellectual Property (“IP Law”), information on “active ingredients” and “strength of medicine” may be considered as “trade secrets” (if the information is kept secretly and has never been disclosed before by pharmacies, manufacturers, etc.). General conditions for protection of trade secrets are found in articles 84 and 85 of the IP Law. The requirements of VPP on the provision of information on “active ingredients” and “strength of medicine” may be in contravention of the IP Law of Vietnam.



Recommendations

We recommend that VPP be legislatively required to implement appropriate measures to protect not only the personal information of patients but also sensitive business data of the hospitals, pharmacies, and patients before such data is provided to the VPP, including:

1. The VPP must establish and publish its own privacy policy in accordance with Article 16 of the Law on Network Information Security;
2. The VPP must receive consent of the patients for the collection and use of their personal information in accordance with Article 17 of the Law on Network Information Security. Personal information, medical history, treatments, medication history, must be treated in a strictly confidential way, except for qualified requests from authorized authorities. No one can disclose such information. The patient has the right not to disclose their personal information in accordance with Vietnamese Law;
3. The VPP must treat the medical records of the patients as State Secrets and protect such data in accordance with the Ordinance on Protection of State Secrets and eventually the Law on Protection of State Secrets (For example: State Secrets can only be copied, scanned, transferred, delivered with approval from a competent authority and in compliance with strict legal procedures as provided in Decree 33/2002/ND-CP dated March 28, 2002);
4. Information stored in the VPP must be categorized and handled in accordance with the law, consistent with its published privacy policy and within the scope permitted by the patient.

III. Medicines covered under the Social Health Insurance are only dispensed via pharmacies at public hospitals which are facing overloading issues, hence increasing patient's waiting time and limiting patient access to their treatments.

Issue Description

Restriction of dispensing of medicines covered by the Social Health Insurance to the public health system can cause inconvenience to patients and negatively impact patient access to their treatments. The Social Health Insurance subsidizes over 1,000 medicines in the Essential Drug List aimed at reducing out-of-pocket payment, increasing patient access to medicines, and consequently improving patient outcomes.

However, these medicines are available for dispensing only at public hospitals and medical stations which normally operate during office hours. Public hospitals are overcrowded and understaffed, which means patients face long waiting time (e.g., sometimes half a day) to obtain their medicines at pharmacies within public hospitals. Many patients choose to pay out-of-pocket instead of using the Social Health Insurance coverage to avoid the long queue, which steers away from the government's directions and objectives. In addition, the pharmacies at public hospitals sometimes have insufficient supply of medicines, especially by the end of the tendering contract, which further delays and restricts patient access to treatments.

Recommendations

The Retail Pharmacy Subcommittee recommends:

1. The government approves for Social Health Insurance claims at retail pharmacies to expand the distribution coverage and increase patient access;
2. The government enhances digitalization of the national health insurance reimbursement system to increase transparency and management efficiency, which will set a foundation for expansion of Social Health Insurance-covered drug dispensed at retail pharmacies.

Government Directive No. 23/CT-TTg dated 23/08/2018; Government Decision No. 540/QĐ-QĐĐĐ dated 20/08/2018; Government Law No. 40/2009/QH12 dated 23/11/2009; Government Circular No. 67/2015/TT-BCA dated 15/12/2015; Government Circular No. 02/2018/TT-BYT dated 22/01/2018; Government Law No. 86/2015/QH13 dated 19/11/2015; Government Law No. 23/2018/QH14 dated 12/06/2018; Government Law No. 50/2005/QH11 dated 29/11/2005; Government Decree No. 33/2002/ND-CP dated 28/03/2002; Government Circular No. 30/2018/TT-BYT dated 30/10/2018.



PRIVATE INSURANCE

Summary of Recommendation

Assess the practice of the Law on Insurance Business and the need to build the amended Law on Insurance Business

- I. Ensure amended Law on Insurance Business and Law on Health Insurance are developed with industry consultation and promotes innovation & investment**

Issue Description

In an effort to modernize and improve the regulatory framework addressing the establishment, operation and financial management of insurance companies, and the provision of cross-border insurance services and insurance auxiliary services, the Law on Insurance Business (Law No. 24/2000/QH10) has been amended twice over the last two decades. While both amendments were successful in narrowing their targets to help open the market to foreign insurers and meet Vietnam's commitments in international agreements, they were also small scale. The Health Insurance Law, passed in 2008 and amended in 2014, provides more specific regulation on the provision of health insurance.

The latest Law Development Agenda (June 2020), states that an amended Draft Law on Insurance Business ("Draft Law") will be submitted for National Assembly first reading in October 2021. This amendment will be broader than previous modifications, seeking to fully align the legal framework with Vietnam's socio-economic development status and international standards. Twelve specific policy areas have been proposed by the Drafting team, including the application of risk-based capital model; changing regulations on establishment and management of insurance enterprises; and allowing enterprises to develop insurance products and services.

The amendment process is well underway, with the Ministry of Justice having appraised an early stage proposal in November 2019. Meanwhile, amendments to the Law on Health Insurance had previously been scheduled for 2020 have been delayed. The Ministry of Health has reviewed the five-year implementation report of the 2015 amendments and is conducting a regulatory impact assessment for further amendments.

Recommendations

As the government of Vietnam its development of the Draft Law, the Insurance Subcommittee would like to make the following recommendations:

1. Engage with industry stakeholders early in the development process and request input from the industry. Insurance companies and industry bodies can support the Ministry of Health and other related agencies in understanding and addressing the challenges facing insurance providers in Vietnam, supporting the development of a positive regulatory environment for investment;
2. The new regulation should support innovation and investment in the insurance sector by reviewing and aligning with international best practices and global approaches to sector regulation. Include standards on risk and consumer protection and support new insurance fields with updated policies. The government of Vietnam can and should develop regulation that best supports the Vietnam context, but by aligning its approach, where possible, with global best practices, new Laws can position the insurance sector for growth;
3. The regulation should promote digital transformation and customer-centric approaches across insurance. In digitalization, new policies and regulation can support ‘digital-first’ customers through ‘insuretech’ that brings down costs and provides easier access to insurance for younger or first-time buyers. New technologies can also reduce approval timelines and increase competition and transparency.

Government Law No. 24/2000/QH10 dated 09/12/2000.

Civil Code No. 91/2015/QH13 of November 24, 2015

Investment Law 2014, Law No. 68/2014/QH13

Law on Protection of Consumer Rights, (No. 59/2010/QH12)

1Decision No. 242/QĐ-TTg of the Prime Minister dated 28February 2019 approving the Plan on Restructuring the Stock Market and the Insurance Market until 2020, oriented toward 2025 (Decision No. 242).



LABORATORY DIAGNOSTICS

Summary of Recommendations

- I. Holding a forum with business leaders across the healthcare ecosystem and solicit feedback about specific complex and unnecessary regulation and take a more “patient-first” approach to regulations
- II. Putting in place regulations that will require low-volume laboratories to comply with stricter quality standards and eventually consolidate to higher volume operations as is common in more developed markets.

Advocacy Issues

- I. The existing laboratory diagnostics regulatory requirements are complex and technically unnecessary.

Issue Description

The Ministry of Health’s facility and licensing requirements oftentimes include provisions that are difficult to implement and technically unnecessary for the reliable delivery of healthcare services, including diagnostics. Because foreign-owned healthcare providers are more conservative than their local peers they may be at a competitive disadvantage when applying regulations to their operational strategies. Currently the Ministry of Health mandates are highly restrictive and do not reflect or accommodate prevailing global business models for diagnostics, lab services, and many other healthcare service sectors. This results in slower growth and discouraging investment (especially FDI) due to the challenges of evaluating how to bring new business models to market in a complex regulatory environment.

Recommendations

We recommend that the Ministry of Health hold a forum with business leaders across the healthcare ecosystem and solicit feedback about specific complex and unnecessary regulation and take a more “patient-first” approach to regulations, focusing on true indicators of service quality as opposed to the current requirement-based regulations.

II. There is a tolerance of low-volume/ low-quality laboratories that needs to be addressed to promote quality & safety

Issue Description

Currently the Ministry of Health does not make any distinction between low-volume and high-volume laboratories and treats both equally. This is highly unusual globally because low-volume laboratories can rarely meet true quality benchmarks and are disproportionately motivated to cut costs at the expense of quality and obscure technical errors. Many scandals have surfaced in the past year directly highlighting this issue.

Recommendations

We recommend that the Ministry of Health put in place regulations that will require low-volume laboratories to comply with stricter quality standards and eventually consolidate to higher volume operations as is common in more developed markets.



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With Appreciation,

Chris Blank & Jonathan Moreno

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