



A Partner in Promoting Health and Wellness in Vietnam

2024 HEALTHCARE COMMITTEE WHITE BOOK

American Chamber of Commerce in Vietnam HCMC

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EXECUTIVE SUMMARY

“We are a key strategic partner for promoting health and wellness and shaping the healthcare industry in Vietnam”
AmCham Healthcare Committee Vision

AmCham’s Healthcare Committee commends the Vietnamese government for its commitment to quality healthcare for all Vietnamese people. Our member companies share common goals, becoming key partners in improving disease awareness, ensuring supplies of high-quality healthcare products, and enhancing the quality of medical services across Vietnam.

AmCham also has been a strong advocate for U.S. vaccine diplomacy, and we are grateful for the generous U.S. government vaccine donations to Vietnam, and the long-standing U.S.-Vietnam health partnership. Vietnam’s impressive, coordinated COVID-19 vaccination rollout campaign has enabled the safe border reopening and strong economic recovery now underway.

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. With these changes, issues related to health in the population are shifting towards non-communicable diseases.

We welcome Vietnamese government healthcare policy goals 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 Vietnamese people and those living and traveling in Vietnam.

AmCham Healthcare Committee members represent global healthcare leaders across a diverse range of industries, including: consumer health and wellness; healthcare technology; hospitals and clinics; innovative pharmaceuticals; medical devices; retail pharmacies; private insurance; 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, we are increasing access to top-quality, innovative healthcare products and services. In addition, our companies and staff are leaders in giving back to communities where we live and work, investing in corporate social responsibility programs to promote health and wellness throughout Vietnam.

The objective of this White Book is to highlight opportunities for partnership to promote health and wellness in Vietnam. The three issues identified below are central to that aim:

Top advocacy issues

- 1. Healthcare Product Access:** Streamline registration and reimbursement processes for faster affordable patient access to innovative, life-saving and high-quality healthcare products (including consumer healthcare products, medicines, vaccines, medical equipment and medical devices)
- 2. e-Commerce:** Establish a policy framework to strengthen regulations for e-commerce (including online pharmacy sales) and e-labeling to protect public health and safety and improve patient access to healthcare products
- 3. Pharmacy chains:** Establish a policy framework to replace the abolished Circular 03/2009/TT-BYT, especially for the scope of activities, priority rights, and preferential policies for GPP-licensed pharmacy chains, to help facilitate retail pharmacy chains’ operation and growth while strengthening governance in pharmaceutical activities management.

INTRODUCTION TO THE AMCHAM HEALTHCARE COMMITTEE WHITE BOOK FROM THE CO-CHAIRS

The AmCham Healthcare Committee is proud to be a part of Vietnam's healthcare ecosystem. We commit to serve as a key strategic partner to promote health and wellness for all Vietnamese people. We will continue to partner with Vietnam organizations to maintain sustainable access to affordable, innovative, and life-saving drugs and medical devices, and quality nutrition products. We will also continue to invest in the future of healthcare management and innovation in Vietnam.

During the pandemic, we partnered to fight against COVID-19. In addition to being strong advocates for U.S. vaccine donations, our members worked side-by-side with the Department of Health on tasks ranging from procuring much-needed equipment and supplies, to inoculating the public. Throughout the pandemic times, with guidance from this Committee, AmCham CARES contributed thousands of Personal Protective Equipment sets, before they were widely available, as well as much-needed equipment such as PCR (polymerase chain reaction) testing and analysis equipment, an ambulance, ventilators, syringe pumps, and patient monitors. Our members will continue to support Vietnam with critical life-saving drugs, medical devices, healthcare services and equipment as we enter a more endemic phase of COVID-19.

Members of AmCham Healthcare Committee do not merely view healthcare as a business opportunity, but also as a commitment to improve the wellbeing of society. Our members believe 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 AmCham Healthcare Committee recognize that our members share common goals to improve Vietnam's healthcare system. As such, we are excited to align and support 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 partnerships.
- 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 reasonably, safely, and efficiently.
- 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 AmCham Healthcare Committee, namely Consumer Health and Wellness, Healthcare Technology, Hospitals and Clinics, Innovative Pharmaceuticals, Medical Devices, Private Insurance, and Retail Pharmacies. 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 AmCham Healthcare Committee's diverse membership, there are a wide range of perspectives. Yet, all of our members are dedicated to our committee vision, and this white book reflects our shared commitment and joint recommendations.

As the pandemic becomes more endemic, we have adjusted to a new normal, with Vietnam's high vaccination rates enabling a policy of "living safely with the virus." With the resolve and sense of purpose forged in fighting COVID-19, we now can focus on partnering with Vietnam to promote health and wellness in Vietnam, supporting the critical goals set forth by Vietnam's Ministry of Health. Our top three recommendations are noted in the Executive Summary.

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

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

Thank you for taking the time to read, review, and consider the information from our second annual white book. We believe this white book will be helpful to understand the capabilities of AmCham Healthcare Committee members and the opportunities and challenges we face as we seek to promote health and wellness in Vietnam.

For Health,



KEVIN DOAK
Co - Chair



LUKE TRELOAR
Co - Chair



KEY ADVOCACY ISSUES BY AMCHAM HEALTHCARE SUB-COMMITTEES

CONSUMER HEALTH AND WELLNESS

Summary of Recommendation

- I. **Regulations:** Improve access to consumer healthcare products within pharmacies via improving regulatory processes, using e-registration end-to-end processes and an implementable General Sale List (GSL).
- II. **Digital edge:** Consider using digital technology such as e-commerce and e-labeling for better access to healthcare products and make healthcare easy with quality control measures and governance.
- III. **Education:** Enhance education/awareness on selfcare through proper nutrition and healthy lifestyle to improve prevention of illnesses, launch more public health fitness programs to gamify healthy lifestyle choices through public private partnerships.

I. There is a need for regulation improvement for consumer healthcare products in terms of approval timeline for all registration types (including new registration, renewal and variation), e-registration end-to-end processes, advertisement procedures and sales of consumer healthcare products at non-pharmacy businesses.

Issue Description

We highly appreciate the efforts of the Ministry of Health in issuing the draft of the Amended Pharma Law for public consultation on November 20, 2023. We recognize that many recommendations (reliance, registration procedure simplification, e-commerce, etc.) from businesses have been absorbed and added to the Draft. We hope that during the review process by the government and National Assembly, the amended Law will be completed to create increasingly favorable conditions for related businesses to operate in Vietnam.

In early 2023, the government issued Resolution 80-/2023/QH15 providing Marketing Authorization (MA) extensions for drugs or drug materials to December 31, 2024. The Ministry of Health has issued Circular 29/2020/TT-BYT, and Circular 08/2022/TT-BYT to amend and supplement Circular 32/2018/TT-BYT, by putting in place an action plan to develop legal documents on health, which solve critical challenges that businesses are facing. In Clause 6, Article 8, Circular 08/2022/TT-BYT, the quantity requirement of marketing authorizations for drugs of the same manufacturer with the same active ingredients or herbal ingredients causes many difficulties for business because there are many drugs with the same active ingredient, content, dosage form, route of administration, but different in excipient composition such as eye drops with different preservative contents, syrups (sugar, less sugar, no sugar, etc.) or medicines for children with different flavors (orange, lemon, strawberry, etc.).

The facts remain that consumer healthcare and supplementation products (i.e., Vitamins, Minerals and Supplements (VMS), functional foods, and healthcare products) are mostly out-of-pocket purchases which have direct positive financial impact to domestic spending. In the pandemic and endemic situations, such products and selfcare can be considered as effective solutions to help people better manage their health and wellness.

Along with reasonable processes for food supplements, the approval timeline for all type of registration process

(including new registration, renewal, and variation) needs continued improvement to better support business operations. Current requirements to secure visas for healthcare products per stock keeping unit (SKU) are a bit taxing for the industry. In Article 36 to Article 39 of Circular 08/2022/TT-BYT, the timeline to review and approve is clearly defined. However, it is not respected in practice and much longer than in regulation. In Article 33, Point 2 of Circular 08/2022/TT-BYT, simplified validation procedures are applied if drugs meet four conditions (manufactured in a factory that periodically undergoes Good Manufacturing Practices (GMP) inspection by Drug Administration of Vietnam; in the list of over-the-counter (OTC) drugs; not directly applied to the eyes; the dosage form of the drug is not modified-release). In this case, it is understood to apply for OTC drugs manufactured locally. However, in practice, there are few cases to get the simplified validation procedure.

Within ASEAN, Malaysia and Singapore are countries with a more open environment for healthcare products.

In Malaysia, the Drug Control Agency (DCA), under Malaysia's Ministry of Health (MOH), oversees drug registration. Applications can be submitted to the DCA online via the Quest 2 system. Some certain types of OTC products are eligible for an abridged evaluation while all other pharmaceutical products must undergo an entire evaluation via the DCA prior to approval. The estimated timeline for abridged evaluations is around 180 days¹. Renewal of the product registration shall be done no later than six months prior to expiry of the product registration. All marketing activities for OTC products are regulated by the Code of Conduct for Non-Prescription (OTC) Products issued by the Pharmaceutical Association of Malaysia and must conform to all existing governmental legislation governing the practice of pharmaceutical industry in Malaysia².


Vietnam has recently allowed basic safe and effective medicine (for minor ailments) to sell in non-pharmacies from 2017. However, there are challenges from the regulations in the Circular No. 07/2018/TT_BYT on general sale list (GSL) medicines and the requirement of GSL shop authorization in Vietnam. GSL medicines are only permitted to sell in non-pharmacies shop which have received authorization on GSL selling activities. There are two requirements which are not practical for implementation:

- A person who possesses a primary pharmacy diploma or higher level [be] in charge of professional activities at non- pharmacies stores (Article 35.2)
- The criteria for including products on the list of drugs remains unclear, as currently there is no defined criteria for medicine which can be switched from pharmacy medicine into a GSL drug

In Singapore, General Sale List (GSL) medicines include GSL therapeutic products and other medicinal products such as Chinese proprietary medicines, traditional medicines, homoeopathic medicines, quasi-medicinal product, medicated oil and balms, which can be purchased off the shelves and are deemed to be sufficiently safe to be used by public without medical supervision. GSL medicines under allowed conditions can be supplied via an automatic vending machine. In Thailand, Drugs which are not classified as dangerous drugs would be traditional drugs or household remedies that are specifically listed by the Ministry of Public Health as drugs that patients may buy without having a pharmacist dispense them.

Medicine classification in Southeast Asia:

Singapore	POM (prescription-only medicine)	✓	P (Pharmacy)	✓	GSL (General sales list)
Malaysia	Rx		Poison / non Poison		OTC
Thailand	Special controlled drugs (SCD)	✓	Dangerous drug (DD)	✓	Household remedy drug
Vietnam	Rx		OTC		★ New category established in Vietnam
Philippines	Rx	✓	OTC	✓	Home Remedy medicines
Myanmar	Rx		OTC		
Indonesia	Red dot / G (obat keras)	✓	Red dot / G2 (obat keras)	✓	Green dot / F (obat bebas)
Laos	Rx		OTC		
Cambodia	Rx		OTC		
Brunei	Prescription Only Medicines		Pharmacy		GSL

 Reclassification guideline available
 Ref: Self-CARER survey, 2nd Self-CARER, 2015, Thailand + partly update

General stores, no listing needed & no pharmacist needed

GSL medicines are classification of medicines available in general stores

¹ Drug Registration in Malaysia, Thailand, other Asia markets (pacificbridgemedical.com)

² PharmaBoardroom | Traditional Medicines and OTC Products: Malaysia

Recommendations

We believe that consumers will have more choices, as well as continue their spending if healthcare products can be claimed on pack/shelf leading to positive impact to the economy. The government can consider promoting a culture of wellness and self-care by:

1. Streamlining regulation for registration and approval through ensuring timelines, a clear fast track process, e-registration end-to-end process in the implementation of Circular 08 to ensure simplification and transparency and have better access to consumer healthcare products within pharmacies under strict guidance of pharmacists.
2. Abolishing pre-approval requirements for cosmetic, medicinal and food supplement advertisement as in the draft of the Amended Pharmaceutical Law. In the short term, a physical and online approval process of OTC medicine advertisement should be quickly developed to avoid impact to business.
3. Improving consumer access to self-care medicine (GSL products). The requirement for each primary pharmacy diploma at each shop and convenience store should be removed and the limitation of registration numbers should be removed to allow companies to register different variants of drugs to meet the different needs of patients.



II. With technology development and digital innovation, non-traditional access like e-commerce for over-the-counter healthcare products and digital applications will accelerate the development of the pharmaceutical industry.

Issue Description

In the context of the continuous innovation of technology and the unpredictable complex situation of the COVID-19 pandemic in recent years, online shopping has become the choice of many Vietnamese. According to Nielsen, four billion people (53% of the global population) are connected to the internet, while consumers go online longer and more frequently. In Vietnam, the number of connected consumers is predicted to reach 40 million people in 2025. In addition, the study also shows that annual spending by connected consumers in Vietnam will increase from \$50 billion in 2015 to \$99 billion in 2025. And by 2025, it is estimated they will account for about half of total annual consumption.

In Japan, OTC products are allowed to be sold online, except certain drugs that require a prescription from a doctor. OTC drugs are classified according to the levels of risk advised by the pharmacist. The Drug Administration Law of China in 2019 also allows the holders of drug marketing licenses and pharmaceutical enterprises that sell drugs through the Internet (Article 61).

In ASEAN countries, Singapore allows retail pharmacies providing the services of e-pharmacies. The e-pharmacy must be a Singapore registered company to conduct retail pharmacy business. These services are to be hosted on a Singapore domain name. In the Regulation 08/2020 of Indonesia, businesses can sell traditional medicines, supplements and/or cosmetics online. Medicines, Traditional Medicines, Functional Foods, Cosmetics and Processed Foods that are circulated online must ensure to meet the requirements for safety, effectiveness, and quality in accordance with the law and must report periodically as required by law. The Food Drug Administration of Philippines has established an e-Pharmacy regulatory framework that is expected to come into effect in 2024.

We recognize the effort from the Ministry of Industry and Trade to issue Decree 85/2021/NĐ-CP amending and supplementing Decree 52/2013/NĐ-CP on e-commerce to meet consumption trends and better manage e-commerce. In Article 26, Point 4 in Decree 52, the subjects applying e-commerce for trading in goods and providing services restricted from trading or provision of goods and services subject to business conditions, shall comply with relevant regulations on the trading in those goods and provision of those services. However, it still is lacking a legal corridor to allow e-commerce for over-the-counter drugs in the Pharma Law.

We look forward to regulations for OTC medicines to be solved on e-commerce channels. Better access for healthcare products can bring annual savings for customers. An analysis of data from seven European countries estimates that moving 5% of prescribed medications to non-prescription status would result in total annual savings of more than €16 billion.⁴

We highly appreciate the efforts of the Ministry of Health to add e-commerce mode, rights and obligations of business establishments operating e-commerce and e-commerce platforms in the draft of the Amended Law, submitted to the Ministry of Justice for review in December 2023.

Besides, digital applications such as e-labelling will accelerate the development of the pharmaceutical industry. The use of electronic labels has many practical advantages such as enabling faster responses for easy access to information; medical staff and patients can look up information conveniently; more flexibility and cost savings in changing labels; packaging waste reduction; and the ability to include more information and supply chain management improvement with better traceability.

Currently, many countries such as South Africa, China, Germany, Finland, Brazil and Mexico have applied two systems (electronic and paper) in parallel to provide drug information. Singapore has allowed the use of electronic labels for prescription medicines and supplements since August 2019.

In Japan, e-labeling accessed via GS1 barcode has become mandatory since August 2021 and user manuals will be phased out after two years, i.e., from August 2023. Singapore has also issued official guidance for e-labeling since April 2021 after nearly two years of testing, which allows companies to voluntarily implement e-labeling (posted on the company's website) and ditch user manuals when notifying regulators. Many different types of codes are accepted in Singapore's guidelines; however, most companies opt for QR codes because they can be scanned by mobile devices without installing additional software. In 2023, the Drug Administration of Thailand also launched an initiative to set up a hosting platform on its website, and the Philippines is currently reviewing labeling guidelines. On April 11, 2023, Malaysia issued a guidance on e-labelling for pharmaceutical products.

⁴ *Journal of Multidisciplinary Healthcare, "Self-medication practices among Vietnamese residents in highland provinces*

On November 11, 2023, the Ministry of Health issued Circular 23/2023/TT-BYT amending Circular 01/2018/TT-BYT on labeling and package inserts of drugs and medicinal ingredients adding “barcodes, QR code, Data Matrix Code (DMC) or other appropriate code on the label of drugs to retrieve electronic instructions for the use of drugs and perform electronic labeling of goods following the roadmap issued by the Minister of Health.”

Recommendations

To help foster convenience for people to easily access self-care measures, the government of Vietnam should encourage e-commerce for OTC products and digital applications through:

1. Approving e-commerce mode with rights and obligations of business establishments operating e-commerce and e-commerce platforms in the Amended Pharmaceutical Law.
2. Issuing a clear roadmap and guidance on e-labelling systems for businesses to prepare and implement to ensure the most updated drug information in a structured and computerized format.



III. There is a need for better healthcare education and awareness on selfcare to improve prevention of illnesses, and to launch more public health fitness programs to gamify healthy lifestyle choices through public private partnerships.

Issue Description

Vietnamese have habits to use traditional medicine. In urban areas, as many as 76% of Vietnamese practice self-care, and around 60% in rural regions.⁵ However, if handled inadequately, these activities not only fail to maximize the potential of self-care, but they can also cause detriment.⁶ In 2017, there was a case of a 22-year-old man in a Northern province who died after overdosing on paracetamol to self-treat a fever.⁶ The importance of education and awareness is critical, especially during virus outbreaks. The “Suc khoe Vietnam” national program with its communication campaign is highly recognized for promoting healthy living.

⁵ S. Roth, "The Ins and Outs of Traditional Vietnamese Medicine," Culture Trip

⁶ Tuổi Trẻ News, "In Vietnam, over-the-counter medicine poses serious health risks,"

Providing information for healthcare products via advertisement is a popular communication channel to consumers. If consumers are informed timely with accurate information, advertisements can help drive correct consumption behaviors. However, the current advertising approval procedure normally takes up to six months. This delay would prevent consumers from getting timely access to reliable information.

Recommendations

The key to better healthcare for Vietnamese people is better education on how to be healthy. The benefit is not only the individual but their family, community, and the economy more broadly. Specific solutions to consider include:

1. Raise awareness on proper nutrition including food supplements, frequent physical exercise, and selfcare to improve prevention through the National Health Program and Prevention Law. More people can avoid health problems and manage both minor ailments and chronic conditions if they understand about the links between everyday healthy habits (e.g., good nutrition, oral health, and physical activity) and disease.
2. Through public private partnerships, launch more training modules on patient well-being and selfcare for doctors, nurses, pharmacist, and other health professionals to improve knowledge of self-care practices. This can elevate the role of pharmacists in providing trusted health advice and increasing the number of health services available.
3. Better access to health literacy including accurate selfcare information to avoid misconceptions. To achieve this, information must be available at national and local levels in various forms such as high quality trusted digital health information platforms, e-labeling or health prevention and promotion campaigns.



HOSPITALS AND CLINICS

Summary of Recommendations

- I. **Regulations:** Continue to allow foreign medical practitioners (FMPs) to use interpreters when providing care for Vietnamese patients instead of enforcing mandatory Vietnamese language proficiency in the new Law on Medical Examination and Treatment, to induce foreign investment and maintain as a sine qua non for medical tourism.
- II. **Regulations:** Support sharing of best practices with U.S. and other international agencies, to work with Vietnamese authorities to support the creation of an independent industry regulatory oversight body to develop an international standard regulatory code, review cases, adjudicate appeals, and provide industry information.
- III. **Chiropractic:** Adopt and enforce World Health Organization (WHO) guidelines on the practice of Chiropractic in Vietnam, aligning Ministry of Health (MOH) policies with international standards.
- IV. **Medical Tourism:** Support the development of Vietnam as a destination for international medical tourism by helping relevant authorities connect with international organizations for medical credentialing and promotion.



Advocacy Issues

I. 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.



II. Regulations, including credentialing and licensing criteria, in some instances may be viewed as unevenly applied. In some cases, this may be the result of guidance originating from different departments. To help unify industry messaging and provide a single point of contact for oversight, we support the creation of an oversight body like the U.S. FDA. To support exploring such a role, AmCham Healthcare Committee would like to coordinate knowledge sharing sessions between the U.S. FDA and relevant Vietnamese government authorities.

Issue Description

We applaud the efforts of HCMC Department of Health (DOH) and Ministry of Health (MOH) to achieve international standards for patient care, which will be a key component in Vietnam's success as a healthcare destination-of-choice. Currently, Vietnam already has several world-class healthcare facilities that have achieved international accreditation, such as Joint Commission International accreditation, and has many other facilities that offer excellent and affordable care that could achieve international accreditation in the near-term. Some changes in the regulatory infrastructure, however, could further enhance the desired level of quality and give international investors more confidence in expanding their local operations and give patients more trust in visiting Vietnam. The foremost change that would accelerate Vietnam's path to international recognition is to clarify regulations governing the industry to prevent confusion or any perceived operational risk for international investors.



Credentialling is a case in point. As of this writing, there have been reports of clinics operating with differing levels of licenses. This would raise concerns that professionals operating in these facilities may not have the proper level of certification for their respective roles.

To address these potential inconsistencies, the MOH and DOH could review current issued licenses and ensure consistency of enforcement. Doing so would prevent any perception that rules are enforced arbitrarily or unevenly applied. This effort could be further amplified by clarifying the mechanism by which healthcare facilities can seek appellate courts to appeal rulings that may be handed down. This combination of transparency of licensing and clarity of appeals processes will encourage international healthcare organizations to expand investments into Vietnam and give patients confidence in consistency of the quality of care.

Decree No. 117 (on administration sanctions in healthcare activities) covers a broad range of activities in the healthcare sector and empowers a wide range of authorities. This may create the perception of overlapping sanctions, and confusion as to which authority has the capacity to inspect, examine and impose administrative fines. Clarification of this point would be a helpful step in fostering transparency and promoting consistency.

As an example, Article 7 of the Inspection Law provides the following key principles: (i) to ensure accuracy, objectiveness, honesty, publicity, democracy and promptness, (ii) no overlap in terms of the scope, subjects, contents and duration of inspection among agencies performing the inspection function, and (iii) no obstruction to normal operations of inspected agencies, organizations and individuals. We are delighted to see this existing commitment to guiding principles, and view this as a fundamental building block.

Further, the Prime Minister issued Directive No. 20 on rectification of examination and inspection activities on enterprises, which restates the principle (iii) above, and requires that the formulation of the annual inspection plan must ensure that an enterprise must not undergo more than one inspection every year.

In response to the COVID-19 pandemic, the government issued Resolution No. 84 (in May 2020) addressing difficulties in business operations, which requires the inspectors to strictly comply with Directive No. 20, to revisit the inspection and examination plan to decrease the inspections during the pandemic, to change from pre-examination to post-examination, and to not conduct unplanned inspections.

Under the Investment Law, the State must treat investors equitably and introduce policies to encourage and enable investors to carry out business investment activities and to ensure sustainable development of economic sectors.

A fundamental way of addressing these perceived inequities is through a stakeholders' forum through DOH and MOH to review issues, consistency of enforcement, and proposed regulations. Also, since some rulings on individual clinics could be interpreted as arbitrary, an appellate process would help meet international governance standards for fairness and impartiality.

Overall, AmCham Healthcare Committee members are honored and delighted to be contributing to healthcare in Vietnam. We share in the country's pride in a healthcare system that is aspiring to become internationally known and respected.



Recommendations

1. Support sharing of best practices with U.S. and other international agencies, and work with Vietnamese authorities to support the creation of an independent industry regulatory oversight body to develop an international standard regulatory code, review cases, adjudicate appeals, and provide industry information. The structure of this regulatory board should broadly represent stakeholders, including private clinics and hospitals, Ministry of Health, Departments of Health, and international agencies.
2. Strengthen the appellate process for those with adverse findings that, with reason, they do not agree with. The Arbitration Court can also be used for the appeal and oversight functions.
3. Hold regular stakeholder meetings with both local and national health authorities to review performance of the regulators and comment on new proposed regulations and decrees.
4. Enable inspectors to strictly follow principles on inspection under inspection laws, comply with Directive No. 20 and Resolution No. 84, and follow principles on foreign investor protection under investment laws.

III. Some individuals, both foreigners and Vietnamese, are calling themselves "Chiropractic Doctors," performing complex and highly skilled chiropractic procedures, and teaching chiropractic short courses that may fall short of the international standards defined by WHO guidelines. Chiropractic is an internationally recognized, doctorate-level healthcare profession, with established guidelines for education and practice, clearly defined by the WHO.

Recommendations

Adopt and enforce WHO guidelines on the practice of Chiropractic in Vietnam, aligning MOH policies with international standards.

IV. Vietnam aspires to become a world-class healthcare services destination. It has already achieved laudable accomplishments in creating centers of excellence around reproductive health, and many other areas such as dental and cosmetic care. However, more coordination is needed to help Vietnam grow to its potential as a regional hub on the same level as neighboring markets like Thailand and Singapore.

Recommendations

Support the development of Vietnam as a destination for international medical tourism by helping relevant authorities connect with international organizations for medical credentialing and promotion.

INNOVATIVE PHARMACEUTICALS

Summary of Recommendations

- I. **Registration:** Ensure timely registration (including variations) of innovative medicines and vaccines through a clear, simplified, and harmonized regulatory process; apply the reliance pathway recommended by WHO to expedite access for patients.
- II. **Procurement:** Unlock the value of innovative medicines for patient benefit, by ensuring a sustainable and predictable process for tender and price negotiations of originator products; establish a clear legal guidance for self-pay channel to enhance patient access
- III. **Patient Access to New Molecules:** Accelerate the National Reimbursement Drug List (NRDL) update annually or when deemed necessary; consider outcome-based market access and adequate healthcare financing solutions for innovative medicines to ensure equitable and sustainable availability of medicines to patients.

Advocacy Issues

I. A significant delay in dossier review for new drug registrations and variations (e.g., new indications) will directly impact the supply of new and existing medicines.

Issue Description

Vietnam currently falls behind ASEAN markets with the lowest innovative pharmaceutical share across the region. Innovative pharmaceuticals represent 20% by value and approximately 4% by volume¹. In 2012-2021, 460 innovative molecules were registered worldwide. Of these 460, only 9% were registered in Vietnam by October 2022, compared with 20% of the Asia Pacific region². Innovative pharmaceutical registration timelines are around three years which is among the slowest in the world². This results in patients in Vietnam being among the last in Asia-Pacific to access new medicines, especially for cancer and rare diseases².

The dossiers submitted to the Drug Administration of Vietnam (DAV) include new drug registrations, variations of existing dossiers such as new indications, Marketing Authorization (MA) renewals and Innovative Pharmaceutical Product (IPP) listings. The backlog of unreviewed dossiers directly impacts the supply of new and existing medicines to Vietnam. This regulatory delay would consequently impact the availability of medicines for patient treatment according to their medical needs, as well as the lack of opportunities for access to innovative medicines that would improve treatment outcomes and patients' quality of life. Many of these medicines are for the treatment of acute and chronic diseases and some of them only have one registration number on the market and there is no alternative therapy for continued patient treatment.

We applaud the coordinated efforts and steadfast actions of the National Assembly and the government to

1. IQVIA VTMA for Vietnam

2. PhRMA analysis of IQVIA data

ensure health security for citizens, via the issuance of Resolution 80/2023/QH15, which extends the validity of MAs of many medicines and vaccines to December 31, 2024.

We also applaud the support of the government in issuing Decision 1661/QĐ-TTg dated October 4, 2021 in order to simplify administration procedures in the Ministry of Health (MOH), wherein MA renewal is no longer required. However, the draft of the Pharmacy Law revision still mentions the requirement of renewal dossiers submission.

In practice, multinational pharmaceutical companies need 3-6 months to plan, manufacture, change and import medicines to Vietnam after receiving DAV's approvals. Therefore, the predictable and timely review and approval of registrations mentioned above are crucial for companies to make appropriate preparations. Furthermore, the delay of new indication approvals of existing products impacts directly to eligible patients.

At this time, the industry remains very concerned and would like to alert the Vietnamese government about the potential risk to the supply of new and existing medicines, which will result in shortages of both branded and generic medicines, impact patients currently being treated, and affect the entire healthcare system.

Recommendations

To avoid a direct and immediate impact on the supply of medicines, any impact or interruption to the continued treatment of patients and delay patients' access to new indications of existing products while facilitating companies' production planning, we would like to recommend that the urgent review and amendment of Pharmacy Law and relevant Decrees and Circulars should focus on the following:

- Ensure timely registration of innovative medicines and vaccines through a clear, simplified and harmonized regulatory process;
- Remove or simplify the MA renewal procedure in the spirit of Decision No. 1661/QĐ-TTg; and
- Adopt the reliance pathway recommended by WHO in registration.

II. Price Negotiations of originator pharmaceuticals and changes in tender regulations as well as proposed application of vaccine import and export licensing present challenges to the sustainability and predictability of processes for drug procurement, impacting supply and patient access to medicines and vaccines while reducing foreign investment in Vietnam.

Issue Description

Under the current government procurement system, Off-patent Originators (OPOs) are procured through the IPP package. Generic medicines are split into five packages based on quality certification.

Over recent years there has been increased pressure on cost containment to effectively manage the sustainability of the healthcare budget in Vietnam. In 2020, the government agreed, with the support of industry, to proceed with a Price Negotiation (PN) process for IPPs with the goal of ensuring access improvement to innovative pharmaceuticals.

In August 2020, the MOH released Circular 15/2020/TT-BYT which sets out the principles and criteria for formulating and promulgating the list of drugs subjected to PN, including a list of 701 molecules. To date, the effective and anticipated changes within these circulars is creating significant uncertainty for industry to appropriately plan for the changes caused by these developments, because of the impact of potential reduction

rates up to 40% for originators without generics and up to 60% for originators with generics.

While it is agreed that PN is an effective mechanism to manage the healthcare budget, ensure a sustainable healthcare system and increase patient access to innovative medicines, this mechanism must consider multiple factors to avoid unintended and adverse consequences. This includes the magnitude and frequency of the potential price reductions and impacts on the volume of medicine supplied over time. Based on the current proposal, significant price reduction without guaranteeing on quota utilization and uncertain process will lead to a lack of sustainability and predictability. Some innovators may discontinue their Vietnam presence due to the uncertainties. It was estimated that 143 out of 701 products would face possible supply disruption, impacting millions of Vietnamese patients. Furthermore, this impact could result in a 58% reduction in planned industry investment and significant job losses.

Recently, MOH, as the National Regulatory Authority (NRA) for vaccines, has proposed under the current Pharmacy Law revision and legal regulations that registered vaccines can only be imported within a maximum quantity stated in the import license. This requirement comes from WHO's recommendation when NRA assessment was conducted for vaccines in Vietnam according to the Global Benchmarking Tool (GBT). However, the specific contents introduced will create barriers to vaccine trade, and slow down patient access to vaccines, even after an MA has been granted.

Recommendations

To reduce pressure on the healthcare sector and motivate Foreign Investment Enterprises (FIEs) to continue investing in sector development, we would like to recommend that the revision of Tender Decrees and Tender Circulars should:

- Unlock the value of innovative medicines for patient benefit, by ensuring a sustainable and predictable process for tender and PN of originator products;
- Prioritize and complete PN for medicines which are in the NRDL first to save time and resources; and
- Establish clear legal guidance for the self-pay channel to enhance patient access

Regulation proposals on vaccine importation should be measurable, transparent, prompt and not impact the vaccine supply chain and patient access to vaccines. We urge the National Assembly and Vietnam government to carefully consider when revising Pharmacy Law as this regulation may not be necessary for the purpose of controlling the quality, safety and effectiveness of vaccines..

III. A delay in NRDL updating and lack of alternative health financing solutions to address challenges of patient access to innovative medicines impact to sustainability of healthcare system.

Issue Description

In Vietnam, it takes about 6-8 years for new drugs to be widely circulated in the market through the health insurance payment channel from the time it is submitted for MA approval as the MA approval takes on average about three years and listing in the NRDL takes 4-5 years. This is much longer than the length of time taken in other countries.

A medicine is still required to follow a lengthy and complex process to undergo review before being enlisted in the NRDL. In practice, NRDL reviews were only updated every five years in the last 10 years. The most recent update of the NRDL was in 2019. Moreover, the out-of-pocket rate is about 43% according to Vietnam Social Security (VSS) report in 2017, much higher as compared to MOH's objective of 35% in 2025 and 30% in 2030 while VSS runs a budget surplus annually (58,643 billion VND in 2022)¹. This delay slows the patient access to many life-saving innovative drugs such as immunotherapy for cancer treatment.

Understanding the urgent need, the Office of the government (OOG) has officially sent the notice no. 294/TB-VPCP dated September 21, 2022 to the MOH asking for immediate NRDL review and update and this should be annually or when deemed necessary. We understand that the MOH has kicked-off the NRDL review and update process. However, the NRDL review process largely depends on reimbursement criteria circulars and principles of Health Technology Assessment (HTA) guidelines which are under revision. In view of the Vietnam context, several challenges remain for the HTA implementation and evaluation due to lack of local data sources, personnel capability and financial limitation.

Finally, the alternative health financing solutions are currently not in place in Vietnam. While global standards are expanding to apply innovative agreements to create more budget headroom such as Risk-Sharing Agreements (RSAs) or named Managed Entry Agreements (MEAs) including finance-based agreements (e.g., price/volume, treatment capitations, price confidentiality agreements) and outcome-based agreements.

RSAs will allow all parties to achieve the common goals and overcome the challenges, including timely patient access to innovative therapies, effective and sustainable management of the government's or payer's healthcare budget and opportunities for drug manufacturers to re-invest into R&D.

As of December 31, 2022, Vietnam has achieved over 93% of the population to access Universal Healthcare Coverage (UHC)². However, it is noted that despite broad coverage, the benefits of statutory Health Insurance (HI) have not yet met the increasing healthcare needs of patients. Many patients have limited access to effective medical treatments or face higher out-of-pocket spending (43% of all healthcare spending as mentioned above). To address similar challenges, many countries have implemented Supplementary Health Insurance (SHI) to close the gaps that statutory HI is unable to fill. SHI helps to reduce out-of-pocket payments and enable improved access to innovative medicines and treatments under reasonable premiums. The Health Insurance Law which is under revision should include relevant details about SHI.

1. <https://laodong.vn/xa-hoi/quy-bao-hiem-y-te-ket-du-hang-chuc-nghin-ti-dong-danh-muc-thuoc-moi-van-cho-cap-nhat-1255392.laod>
2. <https://conghuong.vn/bao-hiem-xa-hoi-viet-nam-ty-le-bao-phu-bao-hiem-y-te-nam-2023-uoc-dat-9322-280513.html>

Recommendations

1. National Reimbursement Drug List (NRDL)

Implement parallel reviews of registration and reimbursement for innovative medicines approved by reference and stringent regulatory authorities. New molecules may be automatically eligible for inclusion in the NRDL upon MA approval. Furthermore, HTA application in building patient benefit packages should be more flexible and efficient.

To ensure faster patient access to new innovative treatment, we urge the MOH to:

- Accelerate the development and approval process of Reimbursement Criteria Circular and Health Technology Assessment (HTA) guidelines and accelerate the NRDL review process;
- Build regulations for annually NRDL review and update or when deemed necessary following the direction from the OOG;
- Treat HTA like an opportunity to enhance patient's benefit instead of barriers to limit patient access to innovative medicines; and
- Allow simultaneous review of the registration for MA and NRDL submission.

2. Innovative health financing mechanism

The Vietnam government's earlier experiences in using the price confidentiality mechanism to procure COVID-19 vaccine has been observed. However, this could be considered to apply for procurement of innovative medicines aiming to support payers in ensuring healthcare budget sustainability. We respectfully request the government to:

- Develop a legal framework to allow price confidentiality mechanism to implement and apply for innovative medicines as recommended by the World Health Organization (WHO); and
- Reflect the application in current revision of the Pharmacy Law and/or Tender Decree and Tender Circular.

Strong policy direction and robust legal and regulatory frameworks provided by the government will be key to maximize the potential of SHI. As the MOH is revising the Health Insurance Law in line with the direction required by Party Resolution 20 to "diversify health insurance packages, strengthen linkages and cooperation between social health insurance and commercial health insurance", we believe that SHI has strong legal and political grounds. We respectfully request the government to:

- Explore SHI models which should be localized to suit Vietnam's need; and
- Explore alternative funding sources to support healthcare financing, including patient co-pay, private market development, additional health insurance coverage, and reinvestment in healthcare programs and treatment from Sin Tax, etc.

Given the ongoing revisions to the Health Insurance Law and Pharmacy Law by the National Assembly and various government agencies such as the Ministry of Health and the Ministry of Finance, we respectfully suggest that the government:

- Hold quarterly dialogue sessions between the above agencies, US aid agencies, other associations, innovative pharmaceutical companies and healthcare experts to discuss issues that are currently being reviewed.

Given the technical nature of drug reimbursement and complexity in delivery of new funding models, the AmCham Innovative Pharmaceutical Sub-committee would welcome the opportunity to participate in consultation sessions, providing global experts who could share best practices.

MEDICAL DEVICES

Summary of Recommendations

- I. **Reimbursement:** Create accessibility to new services, technologies and medical devices by ensuring appropriate reimbursement.
- II. **Value Based Procurement:** Ensure sustainable and cost-effective Healthcare for Vietnam through the adoption of models with Value-Based procurement as a core proponent.

Advocacy Issues

- I. **The last Medical Device reimbursement circular was released in 2017, with many new medical devices and technical services not yet reimbursed, limiting access to innovative new technologies for Vietnamese patients.**

Issue Description

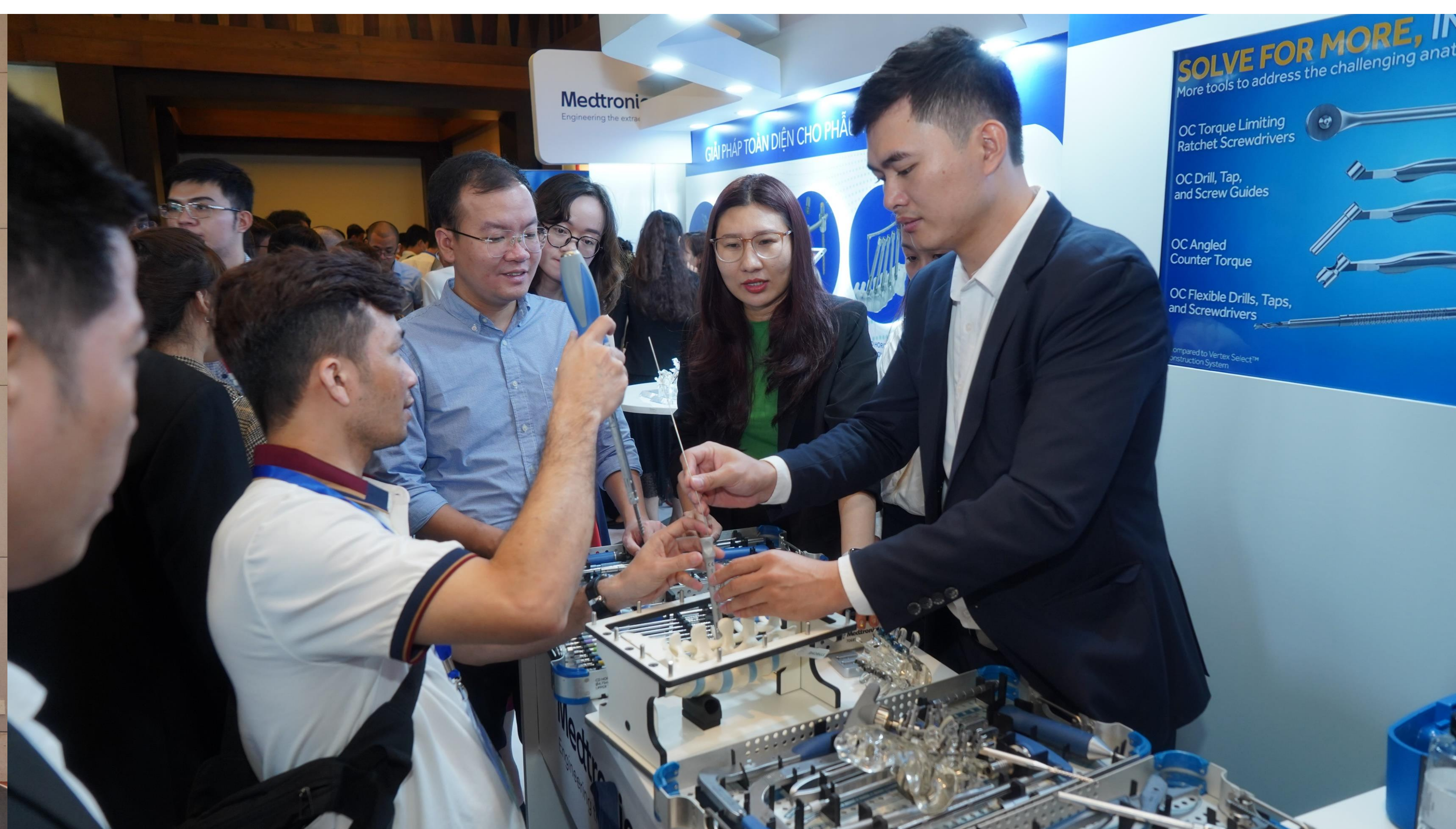
The last Medical Device reimbursement circular (Circular 04/2017/TT-BYT) was released 6 years ago. Since then, many new medical devices have been released and are not yet reimbursed, limiting access to innovative new technology for Vietnamese patients.

To ensure Vietnamese patients have access to new medical devices and technology, we respectfully propose MOH rapidly updates technical services and medical devices in the relevant circulars (Circular 04/2017/TT-BYT; Circular 43/2013/TT-BYT, amended by Circular 21/2017/TT-BYT; and Circular 39/2018/TT-BYT, amended by Circular 13/2019/TT-BYT) and release them for implementation.

Furthermore, we recognize the Health Insurance Law is under revision and we suggest consideration by the National Assembly to allow reimbursement for early diagnostics & screening to reduce the overall burden in the treatment stage (e.g., HPV, Cancer, Chronic diseases etc.).

Recommendations

1. Finalize and release amended Circular 04/2017/TT-BYT incorporating reimbursement for new medical devices, to enable cost effective access for Vietnamese patients to new and innovative medical devices.
2. Finalize the list of Medical Technical Services and collaborate with departments of MOH and VSS to complete the calculation of costs of these services and allow deployment at healthcare facilities nationwide.
3. Allow reimbursement for early screening and diagnostics for cancers and chronic conditions such as HPV, cervical cancer, diabetes, stroke, heart disease etc.



II. Value based procurement ensures a focus beyond price alone. Considering factors such as quality, services and overall solutions can ensure optimal outcomes for patients while reducing the overall cost burden of healthcare. Value based procurement can bring benefits for Vietnam and should be a strong consideration when drafting regulation.

Issue Description

The current procurement mechanism for medical equipment and medical supplies in Vietnam is based on the lowest prices, which may lead to lack of good quality medical equipment and supplies. This can seriously affect treatment results, causing many complications, long recovery times and causing the risk of re-hospitalization and increasing treatment costs. Meanwhile, around the world, procurement decisions have gradually shifted to value-based procurement. Procurement is based on factors such as innovative features, quality, and after-sales service with consideration for patients' clinical outcomes.



Recommendations

Vietnam is currently drafting the first ever Medical Device Law, in addition to guidance for tender process. These documents should have consideration for value-based procurement. Procurement decisions should be based on value factors such as technical differences with impact on the quality of treatment, services and proposed solutions that bring benefits and help achieve clinical goals for patients. Value-based procurement is a patient-centered approach that ensures better, more sustainable quality of healthcare, resulting in cost effective healthcare.



PRIVATE INSURANCE

Summary of Recommendation

- I. **Law:** The amended Law on Insurance Business with effectiveness on 1 January 2023, leveraging global experience in the revisions

Issue Description

In efforts 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.

On 16 June 2022, the Vietnam National Assembly promulgated the new Law on Insurance Business No. 08/2022/QH15, which went into effect on 01 January 2023 except for some requirements that have a transition period, followed by a Decree to be issued to implement this new law. The new law has many improved amendments including the application of risk-based capital models; changing regulations on establishment and management of insurance enterprises; allowing enterprises to develop insurance products and services that add multiple benefits for insured patients and expansion of healthcare services, etc.

After over 30 years of implementing the health insurance policy and more than 15 years since the Law on Health Insurance was enacted, Vietnam is gradually actualizing the goal of universal health coverage. To date, 93 percent of Vietnamese citizens are enrolled in governmental health insurance and 100 percent enrollment is targeted by the government. The Vietnamese government has formulated the Strategy for the Development of Vietnam's Insurance Market to 2030, with the goal of developing insurance entities with strong financial capacity, management capacity approaching international standards, efficient operations and the ability to compete actively in domestic and regional markets. The private health insurance market has much room for development, while health service providers include a mix of public and private sectors. Health insurance reform has supported universal health coverage, and going forward, strong political commitment, administrative capacity and committed sustainable financial resources are essential to the success of such an endeavor.

There are ongoing challenges of implementing the Law of Insurance Business and Health Insurance in Vietnam, when it is facing a rapidly aging population, changing disease patterns, and increasingly advanced health care needs. Against the backdrop of international economic integration, globalization, modernization, and intensifying Industry 4.0, health insurance practices in Vietnam have revealed shortcomings. Adjustments to health insurance policies will help to address such shortcomings and suit the current context.

Recommendations

The Private Insurance Subcommittee, leveraging global expertise, is eager to be a valued partner to the government towards the shared goals of continuously improving health outcomes, while maintaining a good funding balance, sharing best practices from other markets and fostering sector development. We would like to make the following recommendations in the law improvements:

1. Cross-Ministerial agency: The promulgation process of guiding Circulars needs to be overseen by a cross-Ministerial agency to ensure a holistic approach for effective and predictable implementation.
2. Value-based reimbursement schemes: Leverage real world evidence and other value-based models to ensure that the value of new innovative medicine and new disease management solutions is based on value delivery and not only on cost. Set up an agency to research treatments, medicines, and devices that provide the best value for every dollar spent, using health and treatment assessments. Healthcare professionals and stakeholders are invited to benchmark and structure pricing schemes with a cost transparent model.
3. Private sector partnerships: Encourage partnerships and enable a more active role of the private sector: Address the growing middle-class demand through more diversified health insurance packages to increase the optionality and accessibility for patients with diverse needs. Stronger collaboration between the public and private sector together with the sound regulatory framework is necessary to accelerate and streamline the shift to an improved healthcare and wellbeing system.
4. Digital: Link the law with the implementation of the National Digital Health Strategy as digital health will be a corner stone for the transformation of the Vietnamese healthcare system. Technology transfers can help in transforming healthcare to provide universal coverage, the most critical healthcare priority in Vietnam today. The identification of digital solutions as part of this strategy will not only improve access, quality and affordability of healthcare, but also generate competitive advantages that enable Vietnam to create a breakthrough. The proper approach to ease technology and know-how transfers will not only achieve early patient access to high-quality medicines but also ensure efficient public spending on healthcare management.



Recommendations

5. Data: Regulate laws relating to a national database of citizen medical management, electronic health/ medical records to manage the population's health. Rather than replicating the same breadth of services across providers, care is tailored based on a deep understanding of the clinical needs of risk profiles such as geriatric, pediatric, and chronic patients, with technology and big data as the key enablers. The government can partner with technology companies to design a tailored disease management program to better manage chronic patients. General practitioners are incentivized when patients are enrolled onto these programs. Reorganization of the public healthcare system can allow for more patient-centric care focused on the community to deliver more comprehensive and patient-centric health promotion, disease prevention, curative care and rehabilitative care for populations in their respective regions. This initiative is backed by cross-cluster information flow and coordinated services to further enable the MOH to serve as one public healthcare system for the people of Vietnam.
6. Smart personal technology for managing personal health is insufficiently regulated in the law. There is also a lack of awareness of the latest healthcare trends in claim settlement, such as for precision medicine, telehealth-remote care, artificial intelligence (AI) and internet of things (IOT). The private sector invests deeply in research and development through the appropriate use of patient data available to them. Companies that are investing in and developing technologies that directly answer these needs should be encouraged to continue their operations. While there are governmental funding and grant schemes in place for certain types of healthcare innovation research, funding should be made available for untapped areas of innovation that private organizations are exploring.



RETAIL PHARMACIES

Summary of Recommendations

I. Law of Pharmacy 2016 amendment:

1. **e-Pharmacies:** Establish a policy framework to strengthen regulations for online pharmacy sales to protect public health and safety, improve patient access to medicine, promote the development of the e-pharmacy retail industry, and protect job security for qualified and licensed pharmacists.

2. **Pharmacy chains:** Establish a policy framework to replace the abolished Circular 03/2009/TT-BYT, especially for the scope of activities, priority rights, and preferential policies for GPP-licensed pharmacy chains, to help facilitate retail pharmacy chains' operation and growth while strengthening governance in pharmaceutical activities management.

II. Retail pharmacies' involvement to support resolving medicine shortages in public hospitals:

1. Establish a flexible price stabilization mechanism for medicine supply:

- (a) Pilot a Min-Max price procurement mechanism; and
- (b) Allow extending coverage to licensed retail pharmacy chains to dispense medicines subsidized by Social Health Insurance (SHI) to enhance patient access and advance the Vietnamese government's ultimate goals of Universal Health Coverage; and
- (c) Consider implementing a pilot program on medicine price subsidies for preferential and priority beneficiaries.

2. Build an open database for medicine demand forecast and price management, which is regularly updated by hospitals and medical facilities.

Advocacy Issues

- I. There is a need to amend the Law of Pharmacy 2016, particularly related to e-pharmacies and pharmacy chains, to ensure compliance with production and business practices while supporting the business community and state management.**

Issue Description

The MOH is developing a Draft Proposal to develop amendments and supplements for some articles of the Law on Pharmacy 2016 (hereinafter referred to as the Draft) and collecting opinions from concerned parties involved in pharmaceutical activities in Vietnam, including manufacturers, retailers, and importers of medicine, medicinal supplies and vaccines. The formulation and promulgation of this Law aims to promptly remove difficulties and

obstacles related to institutions and laws, to open up and promote resources for socio-economic development in the context of COVID-19 epidemic prevention and control, simplify administrative procedures in investment and business and create favorable conditions for business operation and growth. The Draft is planned to be submitted to the National Assembly in May 2024 and is expected to be approved in November 2024..

I. 1. e-Pharmacies:

There is an urgent need for a policy framework to regulate and control online sales of medicine and support the development of e-pharmacy retailers in Vietnam.

Issue Description

Selling over-the-counter and prescription medicine over the Internet is not currently permitted without a license in Vietnam; however, a wide range of online vendors are operating, potentially causing serious health consequences to consumers, due to

- Origins certificates not registered and granted by the MOH
- Uncertain medicine storage conditions
- Inappropriate delivery methods
- Dispensing practices without prescription and proper consultation from pharmacists

There are four fundamental reasons to support the development of an e-pharmacy policy framework in Vietnam: (1) protecting public health and safety, (2) improving patient access to medicines, (3) promoting the development of an e-pharmacy retail industry, and (4) protecting job security for qualified and licensed pharmacists.

Protecting public health and safety

A critical reason to establish more stringent regulations for online medicine sales is to protect the health and safety of consumers. The existing unregulated online sales of medicine have had and will have dangerous and sometimes life-threatening health effects on consumers.

First, consumers face the risk of being exposed to an uncontrolled and unregulated market of counterfeit, expired, and unclear origins medicines when purchasing pharmaceuticals through the Internet. The use of medicine of substandard quality can reduce treatment effectiveness, exacerbate clinical outcomes, or cause potentially life-threatening adverse events to patients.

Second, although online sales of medicine potentially improves consumer access to medicines, consumers can currently purchase prescription-only medicine from some vendors without providing a valid prescription. Such access to medicine online in addition to self-diagnosis and self-administration of medicines among consumers in Vietnam can cause detrimental public health impacts. Additionally, Vietnam, like other less regulated pharmaceutical markets, is facing a serious and growing problem of widespread antibiotic resistance in the population.

Enhancing supply-side regulations will reduce access to unregistered, unsafe, counterfeit, and expired medicine that are filled and dispensed in unsafe conditions.

Improving patient access to medicines

Online sales of medicine can provide an additional retail channel for consumers and more importantly, can act as an alternative method for retailers, especially modern pharmacy chains, to increase their market penetration complementing their physical presence. Both online and offline pharmacies can expand the consumer coverage of the pharmacy retailer while also improving accessibility to medicine across different consumer subgroups. For urban consumers, online pharmacies can offer added convenience and flexibility, allowing consumers to save time and cost of travel to visit a physical pharmacy location with a level of uncertainty of the availability of product.

Furthermore, online pharmacies can improve the reach of pharmacy retailer services to underserved consumer groups who may experience difficulty accessing medicine from physical pharmacies. The elderly, bedridden, disabled, and consumers in rural and remote areas with limited presence of pharmacies are some of the key demographics that would benefit from properly regulated online pharmaceutical access. Online pharmacies can play an important role to bridge the gap in access for underserved consumer groups while providing services with equivalent quality to services provided at physical locations.

Promoting the development of the e-pharmacy retailer industry

Reinforcement of strict online medicine sales regulations helps provide a safe and controlled business environment for pharmacy retailers to expand online. Large modern pharmacy chains, including Pharmacity, have already acquired business licenses from the MOH to offer online delivery of Over-The-Counter products to their consumers. However, the service offerings of e-pharmacies can be extended beyond simple delivery to cover more value-added services similar to those currently available at physical locations if regulation creates a transparent operating environment for the industry and provides guidance and incentives for retailers to confidently invest in their online operations. Overall, implementing an e-pharmacy policy framework can help foster pharmaceutical industry growth and development in both the short-term and long term.

Strengthening pharmacist job security

The high accessibility to prescription-only medicines over the Internet not using the consultation of pharmacists, poses a risk to the job security of pharmacists. There were approximately 27,540 pharmacists; 70,340 assistant pharmacists and associate degree pharmacist technicians; and 11,439 elementary pharmacists working in Vietnam in 2018. Without a mechanism to supervise and control sales of medicines online, illegitimate online players can easily enter and operate in this pharmacy retailer business, undermining the roles of approximately 62,000 pharmacies as well as 109,310 pharmacists and technicians.¹ This will potentially discourage students from pursuing a career in pharmacies and reduce the pharmacist workforce in Vietnam in the long term.

Recommendations

The AmCham Healthcare Committee's Pharmacy Subcommittee recommends the establishment of a policy framework to tighten the regulations for online sales of medicine in the interests of protecting public health and safety while providing favorable business conditions to protect pharmacist jobs and facilitate the long-term growth of the retail pharmacy sector.

¹ National Drug Administration

I. 2. Pharmacy chains:

A policy framework is needed to replace the abolished Circular 03/2009/TT-BYT, especially for the scope of activities, priority rights, and preferential policies for GPP-licensed pharmacy chains. This can help facilitate both retail pharmacy chains' operations and growth, while strengthening governance in pharmaceutical activities management.

Issue Description

Circular 03/2009/TT-BYT issued by the MOH dated 1st June 2019 giving instructions and regulations on the organization, management and activities of GPP pharmacy chains has been annulled since 2018 by Circular 25/2018/TT-BYT without any replacement as of December 2023. This declaration of invalidity has brought many challenges for pharmacy chains due to no specific regulations or priority rights for their operation and growth while harshening the internal management of pharmacy chain business activities.

Furthermore, some regulations have not been implemented synchronously among provinces and cities, causing struggles during pharmacy chains' scale expansions, for instance:

- Regulations on adjusting the certificate of eligibility for pharmacy business/GPP Certificates in case of any change in the specialist pharmacist representing the pharmacy;
- Regulations on cases subject to re-appraisal of pharmacies (except for the case of assessment of maintaining compliance with Good Pharmacy Practices (GPP) of medicine retail establishments);
- Regulations on licensing related to the sales of products requiring cold storage of 2 - 8 degrees Celsius;
- Regulations on selling of medicine on the list of restrictions from retail;
- Regulations on granting a data-linked account on the National Pharmaceutical Database: Some provincial Department of Health grant accounts within 3 - 6 months following the issuance of certificate of eligibility for pharmaceutical business or GPP certification. After subsequent operations, not all data can be uploaded to the National Pharmaceutical Database;
- The online public service system has not been implemented synchronously among provinces and cities (in terms of submission method, composition, and content of the application).

In comparison to small private pharmacies, the pharmacy chain model operates on a large scale with high coverage nationwide, offering diverse medicine ranges while providing many add-on services for consumers. The growing trend of the pharmacy chain model can simplify state management as all pharmacies under chains are managed to operate according to a unified system of quality standards and modern management systems to ensure quality control and compliance of all business activities.

Recommendations

The AmCham Healthcare Committee's Pharmacy Subcommittee recommends a policy framework replacement for the abolished Circular 03/2009/TT-BYT, especially regarding the scope of activities, priority rights, and favorable policies for the operation of GPP-licensed pharmacy chains in comparison to individual private pharmacies. Specific mechanisms and regulations for this model of pharmacy can help facilitate both retail pharmacy chains' operations and growth while strengthening governance in pharmaceutical activities management.

II. 1. Retail pharmacies' involvement can support resolving medicine shortages in public hospitals. A flexible price stabilization mechanism for medicine supply is needed, including:

(a) Pilot a Min-Max price procurement mechanism; and

(b) Allow extending coverage to licensed retail pharmacy chains to dispense medicines subsidized by Social Health Insurance (SHI) to enhance patient access and advance the Vietnamese government's ultimate goals of Universal Health Coverage; and

(c) Consider implementing a pilot program on medicine price subsidies for preferential and priority beneficiaries.

Issue Description

According to the results of MOH's inspection delegations under Decision No. 2183/QD-BYT and reports from provincial governments, most medical facilities witness shortages of medicine, medical supplies and equipment, but to varying degrees. It is reported that around 90% of central public hospitals witness shortages of medicines, medical supplies, and equipment, especially in emergency, intensive care, cardiology, and surgery departments. In hospitals at lower levels, there is a shortage of medicine during the transition period between bidding packages due to a slow and low supply of vendors. Shortages of medicines to serve a complete chain of healthcare services also occur at public hospitals under Ho Chi Minh City management, while still available in the private market.

The lack of medicine is especially prevalent for the following cases:

- Over-the-counter (OTC) medicine, and medicine with small value or insignificant demand, that have not been supplied by suitable contractors;
- Rare and high-value medicines with complicated, lengthy or unclear import procedures;
- Medicines during the contract transfer period or having unusual rising demand that the medicine supply under the signed contract cannot cover;

Main causes of medicine shortage:

- *Obstacles in procurement mechanisms, policies, and laws:*

- Passiveness and delay usually occur during the medicine bidding process under the lists of price negotiation and national centralized bidding, due to long waits for the results from the National Central Medicine Procurement Center. Hospitals' active bidding can possibly lead to payment difficulties if the National Central Medicine Procurement Center has a lower bidding price;
- Entanglements in self-procurement arise from unclear regulations for vendor selection between using the government budget (Social Health Insurance - SHI) and using available sources of medical examination and treatment establishments, due to differences in the nature of budget sources.

- ***Obstacles in procurement organization and implementation:***

- There is a lack of human resources or experts to participate in medicine bidding, along with the hesitation of the direct implementers or leaders of medical examination and treatment facilities.
- Due to existing debts with vendors due to late settlements from SHI, vendors choose not to participate in the bidding, or are not willing to deliver, or deliver within a very limited quantity and only sufficient for a short period of time.

- ***Obstacles from vendors and suppliers:***

- No vendors participate in bidding for items with limited quantity, or when the market price has fluctuated compared to the planned price, or the quantity and value are limited and cannot cover the cost of medicine bidding and supply.
- Vendors stop providing medicine when the hospital's debt is pending;
- The winning supplier is exclusive and is not willing to supply some medical examination and medical facilities.

Universal Health Coverage and Social Health Insurance

The ultimate goals of Universal Health Coverage (UHC), as defined by the World Health Organization, are to provide *“all individuals and communities the health services they need without suffering financial hardship...[including] a full spectrum of essential, quality health services, from health promotion to prevention, treatment, rehabilitation, and palliative care across the life course.”*

Vietnam has successfully made significant strides in reaching UHC over the past decades. Since 2009, the Law on Social Health Insurance No. 25/2008/QH12 has established the National Social Health Insurance (SHI), which has touched over 90% of Vietnam's population. However, a number of issues and challenges remain unsolved in the way of completely achieving the ultimate goals of UHC. One typical issue is that nowadays, hospitals often run out of medications, and patients have no other choice but to purchase these medications from retail pharmacies, knowing that their bills would most likely not be covered and reimbursed under the SHI.

As a matter of current law, the SHI only covers costs of medical examination and treatment, function rehabilitation, regular pregnancy check-ups and birth giving at the medical facilities which have signed deals with health insurance agencies. Due to the fact that retail pharmacies are not defined by the law as medical facilities (because pharmacies do not provide medical examination and treatment services), only the costs of buying medications from medical facilities (such as hospitals) are covered by the SHI. Vietnam Social Security has, indeed, confirmed this rule, noting that *“there is no [legal] basis for Viet Nam Social Security to refund the expenses [for buying medications from pharmacies] to the insured.”* Once the insured could not be funded by the SHI to purchase medications, the ultimate goal of UHC, as mentioned above, is quite far from being achieved.

Furthermore, public hospitals are often overcrowded and understaffed, which means patients face long waiting times (e.g., sometimes half of one day) to obtain their medicines. Many patients choose to pay out-of-pocket instead of using the SHI coverage to avoid the long queue, which steers away from the government's UHC directions and objectives.

To address those problems, the Vietnamese government has consistently instructed hospitals to stock up on SHI-covered medications to ensure the availability of necessary medications for the benefits of patients. That approach, however, may trigger other issues that hospitals incur additional operating expenses to purchase and

preserve medications, and in some cases, the cost of expiration if any which is not covered by SHI. To pay such extra expenses, the hospitals may need to increase service charges or reduce other costs that may affect operation effectiveness and quality of health services. Furthermore, if hospitals are left to address this issue on their own, the problem is likely to persist or worsen as the list of SHI-covered medications has been and will be expanded over the time for the purposes of achieving UHC.

Preferential and priority beneficiaries

Preferential and priority beneficiaries are defined as those living under difficult circumstances defined in government policies and meet a number of specific criteria required by the law. They are entitled to national social benefits including people living with low income or extremely difficult circumstances, ethnic minorities, veterans or people with meritorious services to the revolution, people with disabilities or affected by Agent Orange/ dioxin, etc. Aside from that, preferential and priority beneficiaries may face struggles in many aspects of life being given priorities, assistance and incentives in education, healthcare, etc. to give them precious opportunities to improve life conditions. In a broader view, this can ensure national sustainable development, support equality and justice between people in society and guarantee social security. Through assessment of real-life aspects as well as the current situation of citizens nationwide, certain changes or new policies in healthcare should be considered for preferential and priority beneficiaries.

Especially in the healthcare sector, in some cases that medicines are out of stock at hospital pharmacies, preferential and priority beneficiaries are unable or not willing to pay or obtain medicine from pharmacies outside of the medical examination and treatment facilities as they must use their own personal expenses, which clearly, cannot be reimbursed by Social Health Insurance. As a result, this can create further financial burden for them and against the government's directions and objectives on ensuring equality in healthcare for every citizen.

Recommendations

The AmCham Healthcare Committee's Pharmacy Subcommittee proposes a number of solutions to overcome the current shortages of medicine in the short, medium and long term.

In the short term, we recommend to focus on solutions to immediately solve the shortage of medicine in public hospitals such as (II.1) a flexible price stabilization mechanism, considering to (II.1a) pilot a Min-Max price procurement mechanism; (II.1b) promote the connection of online health insurance payments with the system of private pharmacy chains and (II.1c) offer a medicine price subsidy budget for preferential or prioritized beneficiaries. With the support of mechanisms and the companionship of the business community, it is strongly believed that these solutions will quickly improve the medicine shortage in public hospitals.

(II.1) Establish a flexible price stabilization mechanism for medicine supply:

(a) Pilot a Min-Max price procurement mechanism on the basis of market prices flexibly updated by suppliers and approved by competent authorities. Retail pharmacy chains such as Pharmacity can connect suppliers or participate in tariff reviews, according to the approved updated market price bracket. However, with a compulsory condition of establishing a database for either suppliers or vendors to regular update, this can be considered as a basis for comparison and approval of price ranges.

(b) Allow extending coverage to licensed retail pharmacy chains to dispense medicines subsidized by Social Health Insurance (SHI) to enhance patient access and advance the Vietnamese government's ultimate goals of Universal Health Coverage

We recommend that retail pharmacy chains be allowed to dispense medicines subsidized by SHI, and that SHI agencies be permitted to cooperate with retail pharmacy chains and to pay costs for buying prescription medications from retail pharmacies to enhance patient access and advance the Vietnamese government's ultimate goals of Universal Health Coverage. This approach will relieve hospitals' burdens on the costs of stocking up on a large quantity of medications. The hospitals can shift their focus on how to improve their services.

Some may be concerned that in case the SHI covers the costs of purchasing prescription medications from retail pharmacies, the SHI fund may be at risk of overspending when the price of medications purchased from retail pharmacies are higher than the prices of medications purchased from medical facilities. Indeed, this could be a legitimate concern.

To overcome the concern about the price of SHI-covered medications sold in retail pharmacies, we suggest a similar solution to the case of private medical facilities. The medications sold in public medical facilities (including SHI-covered medications) are required to be in compliance with the governmental rules and legislation on centralized procurement and/or price negotiation. Private medical facilities may participate in centralized procurements or carry out bidding processes to buy SHI-covered medications. If they decide not to do so, the SHI fund would only pay private medical facilities for medications supplied to the insured based on the published result of centralized procurement plans or price negotiation plans. In case the medications are not included in the centralized procurement plan or price negotiation plan, the private medical facilities could be paid based on the result of successful bids of public medical facilities in the same districts¹. Under such a mechanism, the price of SHI-covered medications at any medical facilities should be always at a reasonable cost and acceptable to the SHI fund.

We also recommend that 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 SHI-covered medication dispensed at retail pharmacies.

As a matter of fact, other countries with an SHI model (such as China, Germany, etc.) have adopted legislation that allow the SHI fund to cooperate with retail pharmacies and/or groups of retail pharmacies, and to cover costs of buying medications from retail pharmacies.²

Medications are essential for delivering the ultimate goal of UHC; all Vietnamese people should be able to access the medications as they need, and retail pharmacies can be the key for this objective.

(c) Consider implementing a pilot program on medicine price subsidies for preferential and priority beneficiaries

We recommend the government to consider and pilot a program to use state budgets to "compensate" medicine prices for preferential and priority beneficiaries with the inability to obtain medicines with market prices higher than those announced by the MOH. Pharmacy chains can play a key role by participating in medicine supply at the prices currently prescribed by the MOH to those that are agreed with government. The government can then use the state budget to cover the difference between the prices set by the MOH and the market prices that are updated on the national database.

This recommendation surely will take a long time for piloting and actual deployment. However, if successful, it can enhance equality of healthcare services in alignment with international standards and bring positive impacts to preferential and priority beneficiaries.

II. 2. Retail pharmacies' involvement can support resolving medicine shortages in public hospitals, through building an open database for medicine demand forecast and price management, which is regularly updated by hospitals and medical facilities.

Issue Description

One typical issue remaining nationwide is that there is no solid source of information or a unified platform available for the health sector to reach out for trustworthy information regarding which kinds of medicine are trending or more likely to be prescribed by doctors, or among similar medicines which would more likely be chosen by consumers, what are the market price variances for medicines sold in different facilities, etc. This unclear and unsolved entanglement has always led to incorrect forecasts on medicine demand in the market, leading to redundancy of some while shortage in others.

Recommendations

In the medium term, there is an urgent need to develop an open national database for medicine prices and demand in order to ensure accurate forecast of medicine demand. In case this solution is well implemented, it will support the implementation of medicine bidding more effectively and accurately, contributing to reducing medicine shortages in public hospitals.

We would suggest to build an open database for medicine management with inputs regularly from public hospitals, medical examination and treatment facilities, etc. With the purpose of doing so, research and evaluation of the medicine data management system (i.e., price, demand, trend, etc.) in public hospitals are considered the first steps to move forward. A collaboration of public-private partners to develop an open medicine data management system is an effective way to ensure correct forecast of medicine demand and price management across the market. The business community shall coordinate closely with relevant National Research Institutes to conduct surveys, research and evaluate the current situation, of course with support from the central government and provincial authorities.

Recommendations (long term):

In the long term, given the current situation which is mostly related to the relevant mechanisms and current laws, we recommend that the government, relevant ministries, departments and the National Assembly consider and review for amendment some articles under the Bidding Law in accordance to current characteristics of the health sector as well as the actual operation of public hospitals, to support procurement and bidding to be implemented quickly, efficiently and in compliance with the law of Vietnam.

ABOUT THE AMERICAN CHAMBER OF COMMERCE IN VIETNAM HCMC HEALTHCARE COMMITTEE

The Healthcare Committee has long been an instrumental part of the American Chamber of Commerce in Vietnam HCMC. The AmCham Healthcare Committee serves as a platform for AmCham healthcare members to:

- Network and share best practices and broad expertise of members across the healthcare environment.
- Discuss industry and regulatory developments.
- Identify and advocate for improvements in the delivery of healthcare and healthcare policy in Vietnam.
- Serve as a key facilitator on healthcare for both the U.S. Mission and Vietnamese healthcare stakeholders.



The AmCham Healthcare Committee leverages its 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 United States and Vietnam.

Today, the AmCham Healthcare Committee has turned the Committee into one of AmCham's most dynamic, active, and well-attended committees. There are more than 60 companies actively involved with this Committee.

The AmCham Healthcare Committee's Vision is clear:

VISION STATEMENT

The American Chamber of Commerce in Vietnam Healthcare Committee is a key strategic partner for promoting health and wellness and shaping the healthcare industry in Vietnam.

The AmCham Healthcare Committee also provides leadership to AmCham on health-related corporate social responsibility (CSR) projects. To support the Vietnamese government’s efforts to contain the COVID-19 epidemic, in March 2020, the AmCham Healthcare Committee took the lead in the AmCham donation of 250,000 face masks to the frontline health workers. In May 2020, the AmCham Healthcare Committee coordinated the donation of RNA/DNA extractors and PCR machines to the Ho Chi Minh City Center for Disease Control and Prevention (HCDC). In 2021, the AmCham Healthcare Committee helped coordinate AmCham’s donations of critically needed ventilators and oxygen monitors. Over the years, the AmCham Healthcare Committee has organized AmCham Blood Donor Days and supported AmCham members to prepare for health emergencies.

A unique aspect of the AmCham Healthcare Committee, unlike many other industry groups in Vietnam, is its broad representation across various segments in healthcare. The diversity of the AmCham Healthcare Committee 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 AmCham Healthcare Committee 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 AmCham Healthcare Committee, a cross-functional leadership team structure was established:

2024 AmCham Healthcare Committee Leadership Team

Co-Chair:	Kevin Doak (Sanofi Consumer Healthcare)
Co-Chair:	Luke Treloar (KPMG)
Vice Chairs by Sub-sectors:	
Consumer Health and Wellness:	Kevin Doak (Sanofi Consumer Healthcare)
Healthcare Technology	Francis Nguyen (VMED Group)
Hospitals and Clinics:	Dr. Mason Cobb (Victoria Healthcare)
Innovative Pharmaceuticals:	Darrell Oh (Pfizer)
Medical Devices:	Rachelle Thompson (Baxter)
Private Insurance:	Minh Nguyen (Allianz Partners)
Retail Pharmacies:	Duc Anh Nguyen (Pharmacity)
Supporting Industries:	Lucas Fortier (POC Pharma)
Secretary:	Le Thi Anh Thy (Proctor & Gamble)
Legal Advisor:	Philip Ziter (Russin and Vecchi)
Government Affairs Advisor:	Samuel Pursch (Vriens & Partners)

AMCHAM HEALTHCARE COMMITTEE MEMBERS' IMPACT ON VIETNAM

Committed to the aspirations set forth in AmCham Healthcare Committee's vision, our members actively contribute to developing 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. AmCham Healthcare Committee member companies have been particularly active in increasing access to healthcare services and enhancing quality of healthcare services in alignment with international standards.



Increasing Access to Healthcare

AmCham Healthcare Committee 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 AmCham Healthcare Committee 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 AmCham Healthcare Committee 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 AmCham Healthcare Committee members' investment activities to improve access to healthcare include:

- Consumer Health and Wellness:** Bayer Vietnam has two modern factory facilities in Dong Nai and Binh Duong provinces. Sanofi has long supported the National Pharmaceutical Strategies by establishing a long-term strategic partnership with the Vietnam Pharmaceutical Corporation – Vinapharm over the last 27 years and investing up to \$75 million USD in a new state-of-the-art manufacturing plant in the Saigon High Tech Park. Production volume is around 90 million boxes and expected to grow up to 150 million boxes per year, which allows Vietnamese patients access to high-quality medicines, as well as exporting 20% of production volumes to Asian countries and Australia, contributing positively to the trade balance of Vietnam.



- **Healthcare Technology:** VMED Group has developed intensive medical Information Technology solutions (Electronic Medical Records (EMR), Hospital Information Systems (HIS), Picture Archiving and Communication Systems (PACS), telemedicine, etc.) to enhance the quality of medical examinations and treatment processes in hospitals and clinics. During the COVID-19 pandemic, VMED Group offered essential medical devices for COVID-19 prevention and treatment such as ventilators and monitors, as well as 24/7 technical support to over 1,000 hospitals across the country. Furthermore, VMED Group donated crucial supplies and equipment for healthcare facilities, medical staff and COVID-19 patients, such as High Flow Nasal Cannula machines, 40,000 syringes with needles, masks, medical gloves, protective gear, and disinfectant products.



- **Hospitals and Clinics:** Members (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. The high demand for services in the private sector and its success to date has opened a tremendous opportunity for further investment. Investors from UK and Germany have already inked deals worth hundreds of millions of dollars. 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. The investment climate continues to improve with new leadership at Ministry of Health and its tremendous success in combating the COVID-19 pandemic. This has brought awareness to the rest of the world and a more receptive attitude in Vietnam as the country is now striving for its place at the international healthcare table.

- Innovative Pharmaceuticals:** Members continue to invest in activities to improve access to healthcare. With an acknowledgment of the value of innovation, subcommittee members invest in research and development, local manufacturing and technology transfer and are scaling efforts to support digital healthcare infrastructure. Several members supported charitable contributions to Vietnam Fatherland Front National Campaign for COVID-19 relief. Committee members Pfizer and AstraZeneca have contributed COVID-19 vaccines to Vietnam beginning in early 2021, while MSD supported registration of molnupiravir, the first oral anti-viral COVID-19 medicine granted conditional marketing authorization by the MOH. In addition, in recent years many members have invested as Foreign Invested Enterprises (FIEs). Through current operations, members also invest to support programs for Continuing Medical Education (CME) and other programs to ensure the quality use of medicines.



- Medical Devices:** 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. Committee member Medtronic contributed ventilators for COVID-19 patients at cost, while Committee member Varian provided high-quality cancer treatment equipment.



- Retail Pharmacies:** Pharmacy, a modern pharmacy chain, is growing rapidly with 1,000 outlets located across the country in both urban and rural areas acting as accessible frontline healthcare for patients to purchase quality medicines (both over-the-counter and prescription medicines) in accordance with the regulations of Vietnamese law, receive services from well-trained pharmacists, and obtain reliable health information. Along with nationwide scale, Pharmacy also offers many add-on services to consumers via consultancy hotlines and chatbots with pharmacists on websites. Consumers are entitled to door-to-door delivery nationwide, saving time and travel costs. Furthermore, in the end of 2022, Pharmacy focused on implementing the "Medicine First" project for maximum serving demand for medicines to consumers.



- Supporting Industries:** 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, including COVID-19 testing. 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

AmCham Healthcare Committee 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. AmCham Healthcare Committee 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.

AmCham Healthcare Committee members have enhanced the quality of healthcare services through:

- **Consumer Health and Wellness:** Bayer Vietnam, with the support of the HCM City Women's Charity Association, sponsored 3,000 healthcare items including vitamins and feminine hygiene products, enabling people in the affected areas. MegaWeCare has supported a blood donation camp and a program to donate VND 500,000 per child per month to Que Hong house. Reckitt Benckiser Group Plc. (RB), signed a memorandum with Vietnam's Ministry of Health to launch the OSCAR project on the prevention of neonatal jaundice. RB sponsors 100 phototherapy devices for treatment of neonatal jaundice in 96 province/district-level hospitals in 10 cities/provinces across the country.



- Healthcare Technology:** VMED Group has focused on manufacturing “Made in Vietnam” medical products with international standards, namely high flow nasal cannula (HFNC), auto-disable syringes, in vitro diagnostic devices (IVD), and a wide range of consumables. In 2021, nearly 800 HFNC machines, produced in cooperation with Hanoi University of Science and Technology, were utilized in COVID-19 field hospitals and by Provincial Departments of Health of Vietnam. VMED Group has also endorsed and joined hands on caring for mental health of medical staff and their families with the “Caring the Carers” campaign at Hospital of Obstetrics and Gynecology, Viet Duc Hospital and National Institute of Hematology and Blood Transfusion.
- Hospitals and Clinics:** Quality of care has been increasing at private as well as public hospitals. This has been due to increased funding for the public sector with many of their doctors studying overseas. Likewise, in the private sector quality often has knowledge transfer internationally.
- Life expectancy, general nutrition, and infant mortality have all shown positive trends. However, some conditions have higher rates and poorer outcomes. Rates of diabetes, stroke from inadequately treated hypertension, liver cancer secondary to inadequately treated hepatitis B, and lung cancer due to the 36% of Vietnamese men who still smoke, all remain considerably higher than comparison countries. Most of these problems can be ameliorated through improved professional and patient education. The private sector emphasizes time per patient and its doctors are frequently trained internationally, supporting a structure to educate patients and staff thoroughly, such as extra training for private sector nurses. These factors can enhance the deeper patient education needed, with hopefully improved outcomes as more patients become better educated. A facet of public-private partnership cooperation can be patient education for public system patients through PPP programs specific to healthcare education. AmCham Healthcare Committee members seek ways to cooperate in this endeavor.
- Innovative Pharmaceuticals:** Over the past 60 years in Vietnam, Sanofi worked with hospitals, medical and scientific associations and medical universities to raise disease awareness and provide healthcare providers the latest scientific knowledge and treatments in therapeutic areas such as cancer, cardiovascular, diabetes, consumer healthcare and vaccination. It believes ensuring good quality of care is as important as improving access to healthcare in term of lives saved. Sanofi has also focused on improving access to healthcare for underprivileged communities in remote areas. In 2020, Sanofi donated 1.3 billion VND to Red Cross Vietnam to support people in Mekong Delta who suffer from severe drought for basic care and COVID-19 prevention. Sanofi has been working dedicatedly to broaden the access of Vietnamese patients to a diversified portfolio of innovative medicines. Efforts are to serve thousands of patients each year with diabetes and cardiovascular diseases, to bring around 5 million doses of vaccines (2020), to support 40 rare disease patients since 1997 with a treatment cost value of \$25 million USD and help people to live healthier via consumer healthcare solutions.

- Innovative Pharmaceuticals:** MSD has a more than 25-year track record of making a difference for the people in Vietnam. MSD was the first company to introduce immuno-oncology therapy to Vietnam, providing access to eligible cancer patients through Patient Access Programs in 36 hospitals nationwide by 2022. MSD has also joint sponsored a study with the National Cancer Institute to assess diagnosis and treatment capability of healthcare centers and hospitals, which sets a foundation for developing the national cancer prevention and control plan, that provides a pathway to improve cancer outcomes for all Vietnamese. Besides, MSD has been working with various hospitals and MOH on an Anti-Microbial Stewardship program to address antibiotic resistance, now with 46 hospitals actively participating. Separately, the technical collaboration between the United Nations Population Fund and MSD supported the MOH HPV vaccination program in Vietnam, with a total budget of \$400,000 USD from 2019 to 2023. Meanwhile, the "MSD for Mothers" program, part of the "MSD for Mothers" Global Giving Program, granted the United Nations Population Fund \$1.2 million in 2021–2024 focusing on innovative interventions to reduce maternal mortality in ethnic minority regions in Vietnam. To address blood supply shortage after social distancing time, MSD collaborated with Red Cross to host an annual Blood Donation Day that involved the participation of employees and their family members.
- Medical Devices:** Members set high standards for manufacturing technologies, and while some AmCham member companies are producing and selling medical equipment through distributors in Vietnam, most companies are primarily importing products into Vietnam. Moreover, members like Roche Vietnam, with a combined strength in Diagnostics and Pharmaceuticals, go beyond diagnostics solutions providers – they work closely with healthcare centers on a holistic approach that offers comprehensive diagnostics, treatment, and care for patients. On the improving diagnostics standard and testing quality front, Roche Vietnam also coordinates with prestigious international and local organizations to provide annual training for healthcare professionals across the country. Some of their on-going programs include: The Chemical Pathology Course (CPC) which is designed to update knowledge and advance skills for more than 7,000 laboratory staffs over the past 13 years. Roche Vietnam also partners with National Reference Laboratory (NRL) over the past 10 years to improve the Infectious Diseases testing quality. The partnership brought multiple External Quality Assurance Services (EQAS) programs for core labs, blood banks, microbiology labs including both serology and molecular assays.





- Medical Devices:** Medtronic and the Ministry of Health have signed a memorandum of understanding to elevate healthcare professionals (HCPs) clinical skill sets in intensive care unit (ICU) departments and centers. The program develops and deploys training programs on the use of ventilators for more than 4,000 doctors and medical staff at ICU departments who are directly providing care and treatment for COVID-19 patients at hospitals across the country. These hospitals include facilities in remote provinces such as Cao Bang, Bac Can, Son La, Dak Lak, Ca Mau and Bac Lieu.
- Private Insurance:** Insurance providers (Aetna International, Allianz Partners, Bao Viet GI, Manulife, Pacific Cross) and international auxiliary service organizations (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 AmCham Healthcare Committee members have strongly supported governmental funds for lower income people, welfare activities and growing trees for the 'Green Vietnam Journey' campaign.
- Retail Pharmacies:** Pharmacity, with a strive to become an "Icon of Trust" to consumers, ensures that all its pharmacies comply with the Good Pharmacy Practice (GPP) quality standards regulated by the government and all warehouses comply with Good Storage Practice (GSP) by the World Health Organization 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. In addition, Pharmacity organizes regular training classes as well as cooperates with leading prestigious training organizations in Vietnam and the world, which are Pharmacity's efforts to continuously improve the quality of pharmacists and place more trust in consumers. In the long run, Pharmacity also aims to devote resources to technology innovation and collaboration with technology partners to improve access to healthcare services and medicines for consumers despite their physical locations (such as healthcare through telemedicine).

AmCham Healthcare Committee members have healthcare advocacy initiatives through:

- **AmCham HCMC-U.S. Healthcare Dialogue:** On October 1, 2020, we were excited to hold our first-ever AmCham HCMC-U.S. Healthcare Dialogue. Top-level government speakers, including representatives from the Ministry of Health and the People's Committee of Ho Chi Minh City, U.S. Ambassador Daniel Kritenbrink, and U.S. Consul-General Marie Damour, together with U.S. private sector healthcare leaders, shared their interest and capabilities to strengthen innovative healthcare partnerships and support **“Realizing the Vision of HCMC as a Regional Healthcare Hub.”** At the event, AmCham's Healthcare Committee launched its 2020 Healthcare White Book, highlighting the diverse and extensive capabilities of our members, together with policy recommendations to strengthen Vietnam's healthcare sector.



- **Healthcare Door Knock:** AmCham led its first-ever Healthcare Door Knock in Hanoi on December 2, 2020, organized by the AmCham Healthcare Committee in partnership with the U.S.-ASEAN Business Council. In meetings with Minister of Health Dr. Nguyen Thanh Long, Vietnam Social Security (VSS), and the Ministry of Planning and Investment (MPI), Healthcare Committee members representing leading U.S. healthcare companies shared AmCham's 2020 Healthcare White Book. They expressed gratitude for Vietnam's impressive management of COVID-19 and discussed key areas of cooperation and concern to ensure continued access of lifesaving drugs and medical devices, and ways to partner to develop world-class healthcare here in Vietnam.



- **Healthcare Door Knock (continued):** AmCham looks forward to following up on eight specific areas of potential cooperation identified by Vietnam Social Security and exploring MPI's idea of a joint healthcare cooperation working group with MOH. Healthcare Committee members also valued the opportunity to meet with Vietnamese officials from MOH, Office of Government and VSS, together with Ambassador Daniel Kritenbrink and members of the Embassy Commercial and Economic team at an evening networking reception. As our MPI colleagues kept saying, we see this as just the beginning of a much closer AmCham-Vietnam Healthcare Partnership.



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The AmCham staff and Committee Vice Chairs/Officers in developing the research and content for this book. This specifically includes:

AmCham Staff Lily Nguyen.

Vice Chairs/Officers: Francis Nguyen (VMED Group), Dr. Mason Cobb (Victoria Healthcare), Darrell Oh (Pfizer), Rachelle Thompson (Baxter), Minh Nguyen (Allianz Partners), Duc Anh Nguyen (Pharmacity), Le Thi Anh Thy (Proctor & Gamble)

Legal support: Philip Ziter (Russin & Vecchi)

Finally, we would like to thank the companies who sponsored the production, translation and printing of the White Book.

With Appreciation,

Kevin Doak & Luke Treloar
Co-Chairs

AMCHAM HEALTHCARE COMMITTEE MEMBERS

- 315 Holding Company Pte Ltd (Nhi Dong 315)
- 3M Vietnam Co., Ltd.
- ACC Chiropractic Clinic
- AEGIS Insurance Brokers Co., Ltd.
- AIG Vietnam Insurance Co., Ltd.
- Allianz Partners Vietnam
- America Indochina Management Ltd.
- AstraZeneca Vietnam Co., Ltd.
- Baker & McKenzie (Vietnam) Ltd.
- Baxter Healthcare (Asia) Pte Ltd (The Representative Office in HCMC)
- Bayer Vietnam
- Bureau Veritas CPS Vietnam Ltd.
- Children of Vietnam
- Chubb Insurance Co., Ltd.
- Chubb Life Insurance Vietnam Co., Ltd.
- Dentsply Sirona Vietnam Company Limited
- Digital Age Dental Laboratories Co., Ltd.
- Diversatek Vietnam
- DKSH Vietnam
- DNAnexus, Inc.
- Docosan Vietnam LLC
- Dong Thai Import and Distribution Limited Company
- Ernst & Young Vietnam Ltd.
- FV Hospital (Far East Medical Vietnam Limited)
- General Electric Vietnam
- Given Imaging Vietnam Co., Ltd. (Medtronic)
- GlaxoSmithKline Consumer Healthcare Vietnam Co., Ltd.
- Hoan My Medical Corporation
- International SOS Vietnam Co., Ltd.
- Johnson & Johnson Vietnam
- KPMG Limited
- Lab Group International Vietnam Co., Ltd.
- LNT & Partners
- Manulife Vietnam Co., Ltd.
- Marsh Vietnam Ltd.
- Mead Johnson Nutrition
- Medtronic Viet Nam Company Limited
- Merck Sharp & Dohme (Asia) Ltd. (known as MSD)
- Novartis Vietnam Co., Ltd.
- Pacific Cross Vietnam
- Pfizer (Vietnam) Limited Company
- Pharmacy Pharmacy Joint Stock Company
- POC Pharma
- Procter & Gamble Vietnam
- Representative Office of Abbott Laboratories GmbH
- Representative Office of Beckman Coulter Hongkong Limited in Ho Chi Minh City
- Roche Vietnam Co., Ltd.
- Russin & Vecchi
- Sanofi Vietnam Shareholding Company
- Sanofi-Aventis Vietnam
- Terumo BCT Vietnam Co. Ltd
- Victoria Healthcare Vietnam
- VinaCapital Foundation
- VMED Group Joint Stock Company
- Vriens & Partners
- Willis Towers Watson Vietnam Insurance Broker
- Zeda SG Pte Ltd
- Zuellig Pharma Vietnam Co., Ltd.

ABOUT AMCHAM

AmCham is a not-for-profit, non-governmental, and non-partisan organization that exists to serve our members. We welcome American, Vietnamese, and international companies that share our interest in enabling a fair, transparent, predictable, and efficient regulatory environment that values innovation. Our mission is to promote trade and investment between the United States and Vietnam and serve as the voice of American business in Vietnam.

AmCham is already one of the largest foreign business chambers in Vietnam with over **550** corporate members and **2,000** individual business representative members in AmCham Ho Chi Minh City and AmCham Da Nang, and over 650 corporate members and 2,500 members including AmCham Hanoi. We are a member of the AmChams of Asia Pacific (AAP) and the U.S. Chamber of Commerce.

We strive to continue to be the most strategic, influential, and dynamic business association in Vietnam, driving innovation and sustainable growth, and helping our members succeed. We are committed to diversity, equity, and inclusion, as well as environment, social, and governance values and aim to be a community you want to join!

Join us:

<https://www.amchamvietnam.com/membership-application-procedures/>



AMERICAN CHAMBER OF COMMERCE IN VIETNAM HCMC

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