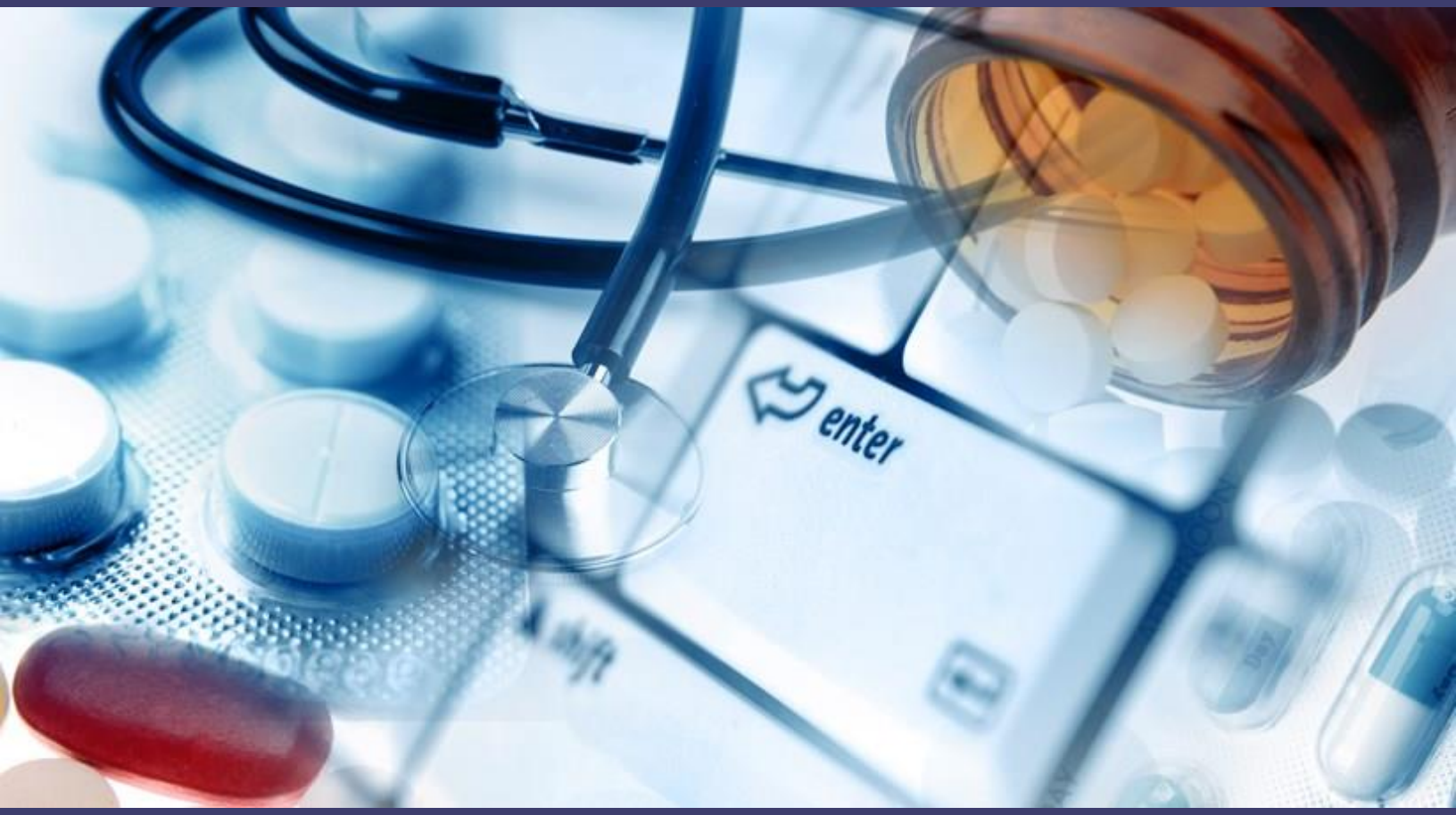
NEWSLETTER

"New Rules, New Game" for Pharmaceutical MNCs



Semiannual Report, August 2018

YKVN

HANOI • HO CHI MINH • SINGAPORE

Without a mechanism to establish a Foreign Invested Enterprise ("**FIE**") engaging in the pharmaceutical industry,[1] the Government has permitted pharmaceutical representative offices ("**ROs**") to conduct their business activities in Vietnam on the basis of "special treatment" and outside the normal scope of permitted activities for ROs. The promulgation of Law No. 105/2016/QH13 on pharmaceuticals, which took effect on January 1, 2017 (the "**Pharma Law**") and Decree No. 54/2017/ND-CP dated May 8, 2017 (the "**Pharma Decree**") has provided a legal framework to establish an FIE to import pharmaceutical products into Vietnam (the "**Import FIE**"). The Pharma Law, Pharma Decree, and the Import FIE have, collectively, revealed the Government's determination to actively "push" multi-national pharmaceutical companies ("**MNCs**") from ROs into Import FIEs. The reasons and consequences of the Government's determination are myriad and include, among others: making it easier for the Government to manage the pharmaceutical industry; giving more autonomy to MNCs; and requiring MNCs to commit to long-term business plans/investments in Vietnam. However, more than a year has passed since these regulations became effective, and, yet, MNCs still seem puzzled about the mechanics of adjusting their business models to comply with the new regulations without running into significant commercial disruptions or legal compliance issues. With the recent introduction of the draft circular regulating the activities of Import FIEs and, particularly, their relationships with local distributors (the "**Draft Import FIE Circular**"), as well as certain official letters from the Drug Administration of Vietnam (the "**DAV**") and the Ministry of Health ("**MOH**"), regulators in Vietnam have provided more guidance on how the Government contemplates Import FIE's will operate. However, there are many issues still outstanding, including whether the Government's plan, in practice, creates a sustainable and commercially viable Import FIE. In this newsletter, we will provide certain information and analysis reflecting the regulatory views of the MOH and DAV, as well as provide our comments on the most recent version of the Draft Import FIE Circular for your consideration and reference. If your company requires any additional information, we would be delighted to advise your local and regional teams on navigating the complex regulatory framework being constructed by the Government for the Vietnamese pharmaceutical industry.

1. The possibility of outsourcing medical representatives ("MRs")

Historically, according to Circular 13/2009/TT-BYT ("**Circular 13**"), ROs could employ MRs as "drug introducers". Accordingly, provincial Service of Health Departments ("**SOHs**") would generally issue MR cards to an RO's MRs under the RO's name. However, with the introduction of the Pharma Law, such employment is no longer legally possible. In particular, according to the Pharma Law, only "pharmaceutical business establishments" (i.e., with a CEPB), which does not include an RO, can employ MRs and issue MR cards to their employees. This view was discussed and confirmed by the DAV and MOH in Official Letter 4338/QLD-PCD dated March 14, 2018 ("**Official Letter 4338**"), as well as in other training sessions on the implementation of the Pharma Decree hosted by the DAV.

[1] DAV Official Letter 13439, issued on July 13, 2018, is not addressed in this Newsletter. However, we do note—after our initial review of the DAV's Official Letter—in our view, the DAV's Official Letter 13439 does not materially impact the discussion and analysis shared in this Newsletter.

The new approach of the DAV/MOH puts the two-decade precedent of MR card issuance to ROs into jeopardy. According to Circular 07/2018/TT-BYT, which came into effect on June 1, 2018, ("**Circular 07**"), MRs holding MR cards before the effective date of Circular 07 (i.e., June 1, 2018) can continue to provide drug information services to HCPs until the expiry date of their MR cards. Up to now, as far as we are concerned, there are 5,000-10,000 MRs currently licensed to work for ROs pursuant to the old legal regime of Circular 13. After our recent discussion with the MOH, the MOH promised that they will consider expanding the transition period for MRs working under employment contracts with ROs and having MR cards issued by such ROs (i.e., ROs can continue to operate under the old legal regime); however, there is still no development on the MOH's consideration of our request for this transition period, which, ultimately, would be extremely helpful to the commercial viability of the RO to Import FIE transition.

On a separate note, while awaiting legislative approval for the 2-to-3-year transitional period, MNCs may wish to find a new "house" for their MRs by way of outsourcing MRs through a service-contract mechanism entered into between them and local distributors/fully licensed importers. However, the law remains silent on the possibility to use MRs employed with another company, whether they are employed by a foreign-invested firm or local entity. By way of such a mechanism, the ROs can (continue to) use the MRs of qualified pharmaceutical business establishments, which have been validly established and entitled to issue MR cards for their own MRs. Nevertheless, when using outsourced MRs, the MNCs will also need to take into account the risk of violating the Foreign Corrupt Practice Act (the "**FCPA**"), especially in cases of the mutual termination of labor contracts between the MR providers and their employees, or the risk of being deemed as engaged in "disguised distribution"; therefore, the MNCs should consult with their legal counsel as they proceed, or contact us for further advice. Advice on such issues will ultimately be determined by the specific risk tolerance of each invidual member of the innovative pharmaceutical sector, and, thus, general advice on such issues will tend to be irrelevant to the individual company.

MRs housed by local partners /FCPA risks

Moreover, the current regulations and Draft Import FIE Circular do not extend their regulated areas to affiliates of Import FIEs (including subsidiaries, the offshore parent companies, etc.), which technically gives rise to the inference that the service-contract mechanism is not prohibited under the current regulations. However, given that the underlying policy under the Pharma Law and Pharma Decree is to prevent any form of "disguised distribution", the enforceability of such contracts remain under a cloud of legal uncertainty. In the future, the MOH and DAV may be further aware of this structure and promulgate other regulations to prevent any potential circumvention from the ROs. However, MNCs would be advised to keep as many of these contracts as offshore contracts as is reasonably possible.

So long as the MNC wishes to directly employ MRs to guarantee the satisfaction of international standards, we believe that **the shift from the RO model to an Import FIE is inevitable**, since the regulations on the scope of operations is regulated by the Pharma Law and the Pharma Decree—the two highest forms of legislation in Vietnam.

2. Establishment of an Import FIE as a new business model

Through an unofficial market scan, 50% of MNCs are operating in Vietnam as an RO. As a matter of law, ROs are not permitted to carry out business/sales activities. In the past, ROs were mainly functioning to provide drug information to healthcare professional organizations or individuals ("**HCPs**") through their MRs. However, under the Pharma Decree, ROs are no longer able to employ MRs. This new regulation presents the intention of the MOH to restrict RO activities within those permitted under the law and may likely result in a shift in the business model of such MNCs from ROs to Import FIEs, either as a wholly-owned company by the parent MNC or a joint-venture between the MNC and a local partner, which local partners would be qualified to conduct pharmaceutical business, i.e., importing pharmaceutical products.

The whole process to establish an Import FIE, which may require a substantial amount of time and money, consists of the following key steps:

a. Investment Registration Certificate (the "IRC")

Establishment Phase. To set up an Import FIE, MNCs must first register an investment project. The application dossier includes, among other components, a request for issuance of an IRC, investment proposal (i.e., explanation of the satisfaction of conditions applicable to foreign investors and the Import FIE under Vietnam's WTO Commitments and Vietnamese law for conditional investment sectors), agreement on reservation of an office space, and supporting documents of the MNCs (e.g., incorporation certificate). The approval of such investment project is in the form of an IRC. By law, the provincial Department of Planning and Investment (the "**DPI**") or management board at an industrial zone/economics zone/hi-tech zone will issue the IRC in favor of the foreign investor within 28 days from the date of its receipt of a complete dossier. In practice, the timeline may be 2-3 months, given that the regulator has complete discretion to decide when an application dossier is "complete".

b. Enterprise Registration Certificate (the "ERC")

Establishment Phase II. Once the IRC is issued, the investor must apply for an ERC to establish the Import FIE. The application dossier includes, among other components, a request for issuance of an ERC, the charter of the Import FIE (which is in the same nature of the articles of associations in other jurisdictions), and a certified true copy of the IRC. By law, the DPI will issue the ERC in favor of an Import FIE within three (03) working days from the date the local DPI receives the complete application dossier. In practice, it may take around 1-3 weeks. After the issuance of the ERC, the Import FIE is required to satisfy several post-establishment obligations.

c. Investment capital

Obligations of Establishment Phase. The investment capital for running the Import FIE is the combination of charter capital, which is contributed by the MNC and other partners (if any), and loan capital, which can be funded by onshore credit institutions or offshore lenders. There is no requirement on minimum charter capital of the Import FIE. In practice, however, the registered charter capital (i.e., equity) should be an amount reasonably sufficient for the Import FIE to run its operations. Further, the capital contribution must be made through a direct investment capital account within 90 days from the date of issuance of the ERC.

d. Operational Sub-licenses

Operational Phase. As importing pharmaceuticals is a conditional business line,

the Import FIE must obtain a Certificate of Eligibility for Pharmaceutical Business (the "**CEPB**") prior to its official operations. Key components to get the CEPB include, among other elements, having a warehouse, which satisfies Good Storage Practice Standards ("**GSP Standards**") under the Import FIE's own name. The statutory timeline to obtain the GSP Standard certificate and CEBP is 30 working days from the date of receipt of a complete application dossier by the Department of Health, and 30 calendar days from the date of receipt of a complete application dossier by the MOH, respectively. In practice, the timeline may be extended to 2-3 months for the GSP Standard certificate and 3-4 months for the CEPB, subject to the sole discretion of the competent authorities.

e. Post-licensing procedures / After Establishment and Operational Licensing

Obligations after Operationalizing. After obtaining the CEPB, the Import FIE is required to carry out certain actions to enable/operationalize their import rights and the distribution of their drugs to licensed wholesalers in Vietnam, including:

i. announcing the Import FIE's wholesalers in relation to each imported drug by submitting a report to the MOH; and

ii. declaring of price of imported drugs to the MOH by submitting an application dossier to the MOH, which must be submitted prior to the circulation of the "first lot" of imported drugs into the Vietnamese market. The statutory timeline for the MOH to review and publish the prices on their website is 45 days. We are not yet aware how long this process will take in practice.

3. More stringent conditions on GSP Warehouse requirements in obtaining the CEBP

GSP certificate should be under the name of the Import FIE.

Provision of logistics services, including, among others, warehousing and transportation services, has been dominated by a few FIE service providers for the last two decades. The service is to ensure international standards in the transportation and storage of pharmaceutical products from international pharmaceutical companies.

The Pharma Law and Pharma Decree require, among other things, the conditions for obtaining a CEPB of an Import FIE, is to have a location, a storage warehouse, preservation equipment, transportation vehicles, quality control systems, technical documents and personnel complying with GSP Standards. However, it is not clear whether the warehouse must be owned by the Import FIE or the Import FIE may contract with a warehousing and transportation service provider who owns warehouse(s) satisfying GPS standards, or, alternatively, whether the GSP certification can be in the name of the Import FIE even though they merely lease the warehouse in question. In Official Letter 4338 and the Draft Import FIE Decree, the MOH expresses the view that Import FIEs may either build their own warehouses for storage of imported drugs or lease warehouses from local companies satisfying GSP Standards. In either case, an Import FIE must be directly in charge of running and managing such a warehouse. The Draft Import FIE Circular, when promulgated, may put an end to the market domination of merely a few FIE service providers in the areas of storage, transportation and other logistics services related to imported drugs.

Another concern implicated by leasing a warehouse, which is GSP-certified, is whether an Import FIE submitting an application for a CEPB is required, as a condition precedent, to lease a GSP-certified warehouse from a local lessor or whether the GSP certification must be under the name of the respective Import FIE. Although there is a continued vagueness under Official Letter 4338, with the combination of both the Pharma Law and Official Letter 4338, it seems an obvious interpretation the GSP certification must be under the Import FIE's name so that the Import FIE would meet the requirement of being "*directly in charge of running and managing the warehouse*".

Though the Draft Import FIE Circular is aiming at foreign invested pharmaceutical logistics service providers, it would also mean that Import FIEs may face the risk of being required to invest a substantial amount of time and money for their own GSP warehouses or such companies will be unable to ensure international standards when using local logistics service providers for their imported products. Thus, this legislation may require Import FIEs, after being established, to turn to contractual remedies for risk reduction. Again, this issue needs to be analyzed on a company level, with full access and knowledge of the risk tolerance of the specific company making the decision.

4. Prevention of "*disguised distribution*"

The Draft Import FIE Circular aims to clarify the scope of "prohibited activities", which an Import FIE is prevented from conducting (i.e., "disguised distribution") for fear that Pharma MNCs will control the entire market and exercise such control in a way that increases the cost of drugs. Under the Draft Import FIE Circular, by way of providing guidance on the implementation of the Pharma Decree, the regulators tend to expand the prohibited activities as wide as possible. For instance, the Draft Circular prohibits any form of financing between an Import FIE and local distributors/wholesalers (e.g., by investing in distributors/wholesalers of the imported drugs, or by directly interfering with the salary/benefits policies of the distributors or wholesalers. Notably, the Draft Import FIE Circular also prohibits an Import FIE from directly receiving orders from HCPs or any organization other than wholesalers—which have been specifically announced and identified by the Import FIE to the MOH (and the MOH will then publish this list on its web portal).

As discussed above, the Pharma Law and Pharma Decree, as well as the Draft Import FIE Circular, seem to ignore the potential involvement of "unrelated parties" with an Import FIE's affiliates (e.g., subsidiaries, offshore affiliates, etc.). This regulatory omission in the legislation is large, signiifcant, and material. Put simply, current regulations do not prohibit agreements entered into by affiliates of the Import FIE, including the offshore parent company, with local distributors to exercise rights, which Import FIEs and ROs of MNCs are currently not entitled to exercise. This regulatory omission in the legislation exists and can be used today. However, conservatively speaking, and given that the MOH is aiming at identifying and stopping "disguised distribution", the MOH may identify this whole in the legislative framework for the pharmaceutical industry. And, if discovered, the MOH may take steps—and is likely to take steps—to amend current regulations to prohibit such agreements—however, it may be difficult for the MOH to regulate those aspects of the agreement(s) that can be kept completely offshore. Therefore, it is advisable for MNCs, Import FIEs, and ROs of MNCs to be vigilant in observing regulatory and legislative movement(s) of the MOH and DAV in dealing with "disguised distribution", irrespective of

the model such disgused distribution assumes, and regardless of its location (i.e., onshore or offshore agreement(s)).

5. Conclusion

With the Draft Import FIE Circular, as well as the issuance of Official Letter 437 and Official Letter 4338 by the DAV and MOH, the Vietnamese Government is clearly taking a more restrictive approach in dealing with the distribution rights of Import FIEs and the provision of drugs information by ROs. While there is some consideration being given to MNCs: for instance, shifting their business model(s) from the RO model to an Import FIE model that will allow, among other things, directly employing MRs and self-issued MR cards. Nevertheless, the new business model contemplated by the Pharma Law and Pharma Decree is not expected to come very fast; instead, a prolonged timeline is contemplated for the establishment and operationalization of a fully-licensed Import FIE, and, during this time, the MOH/DAV retain the discretion to issue additional guidance and Official Letters further prohibiting and restricting the activities of Import FIEs (and, perhaps, their affiliates, both onshore and offshore).

Although the Government approach has been criticized by various commentators and adjustments have been requested by key stakeholders, the Government position appears to dig deeper with each new Official Letter or response to official requests for guidance. While MNCs may come up with certain commercial and contractual mechanisms to overcome some or all of the regulatory restrictions, it is ,nonetheless, advisable for MNCs to closely watch and monitor the DAV/MOH for reactions to such commercial solutions, irrespective of whether the relevant reactions are articulated in an amended law, an Official Letter, or simply in practice—and the practical implementation of the Draft Import FIE Circular and other key aspects of the new regulatory framework for the innovative pharmaceutical sector.

At the end of the day, each MNC must gauge its risk tolerance, its market share, and its business strategy in Vietnam in making decisions about how and when to take certain critical actions within the new regulatory framework for pharmaceutical innovators. Decisions made at the company level will benefit from value-added legal and financial advice, specifically tailored to the MNC's business model in Vietnam and risk tolerance both in Vietnam and globally. There are no right answers, and there is no correct timing for the decisions that must be made by the MNCs; instead, there are answers and there is timing, which is tailored to the business model and risk tolerance of each MNC. This process will require advisors that understand your businesses and know the chief concerns of

regional colleagues. We, of course, would be delighted to advise your MNC or RO in Vietnam.

Please contact Eli Mazur (Founder and Managing Partner, YKVN's Pharma Practice Group), if you, your team, or your regional colleagues have any questions arising from this Newsletter. Eli can be reached in YKVN's Ho Chi Minh City Office, or on his mobile phone — +84 93 789 6443 (offshore) / 093 789 6443.

Disclaimer:

This Newsletter is prepared to raise the general awareness of critical issues in Vietnam's innovative pharmaceutical sector, which have been recently aggravated by a new regulatory framework. This Newsletter aims to update and provide new information to its readers in an organized and succinct form. The information presented is not legal advice and should not be relied upon in making commercial decisions. Instead, individual companies are advised to consult with their legal counsel about any issues raised in this Newsletter that surprise, impact, or are otherwise relevant to their commercial operations.

KEY CONTACTS

Eli Mazur
Partner

For nearly two decades, Eli has been a trusted advisor for multinational companies operating in Vietnam, including in the health and pharmaceutical sector. Eli is the founder and Lead Partner of YKVN's Healthcare and Pharmaceutical Practice Group, and his client base includes the Vietnamese subsidiaries of Pharma MNCs comprising approximately 70% of the domestic pharmaceutical industry by revenue.

Eli originally came to Vietnam in 2003 as a Senior Research Associate, under Thomas J. Vallely, with the Vietnam Program, Harvard University and led the Law and Public Policy program at the Fulbright Economics Teaching Program in Ho Chi Minh City. Before joining YKVN LLC in 2010, Eli spent more than 3 years in the corporate practice of Freshfields' Hanoi office, and Eli's practice included myriad clients in Hanoi, Ho Chi Minh City and throughout Southeast Asia and the United States.

Eli is a U.S. qualified lawyer (Duke Law), a Registered Foreign Lawyer in Vietnam, and is highly regarded by clients as a problem-solver, a crisis mitigation expert, and a commercially-oriented, practical adviser, with the ability to add true value to a company's bottom line with, among other things, his ability to assist clients develop and maintain successful long-term commercial partnerships in Vietnam.

Ngo Minh Hung
Senior Associate

Hung is a future star of the YKVN's Litigation & Arbitration Practice, which is ranked Tier 1 domestic firm by Benchmark Asia-Pacific in 2018. After years of experience and training domestically, Hung had the chance to quickly sharpen his skill and acquire the essential of international arbitration when he joined the Singapore International Arbitration Centre (SIAC) as an intern. He focuses on complex matters and has litigated cases in all level of courts and represented at arbitrations throughout the country.

While still shining in Litigation & Arbitration, Hung directs his focus on Healthcare & Pharmaceuticals Practice and quickly excels in this sector. With his critical reasoning and experience after years of practicing as litigator, combined with his deep understand of the Vietnamese legal framework, he quickly becomes the key leader of Healthcare & Pharmaceuticals Team at YKVN, the go-to lawyer of multinational corporations as well as Vietnamese conglomerates for legal advice and dispute resolution.

Hung recently advised founders of a pharmaceutical manufacturer in a dispute with a strategic investor, a giant pharmaceutical manufacturer whose shares are listed on the New York Stock Exchange (NYSE) regarding various claims on drug registrations and misrepresentation.

Tran Nam Tung
Associate

Tung is a registered foreign lawyer practicing in Vietnam. At YKVN, he focuses on Corporate/M&A and Healthcare & Pharmaceuticals matters. Tung has assisted to advise multinational companies operating in Vietnam, including in the healthcare and pharmaceutical sector.

Beside a Juris Doctor Degree, Tung also has a Master Degree in Business Administration. With his background, Tung has advised multinational pharmaceutical corporations on transnational issues such as complying with FCPA and British Anti-Bribery Act, advising on cross-border business framework to optimize local operations in Vietnam. Tung always endeavors to utilize his business acumen and foreign legal training to give the most practical legal advice to Clients.

Tung is highly regarded by Clients as a commercially-oriented and practical adviser with the ability to assist Clients to develop and efficiently maintain short and long-term business, and investment relationships in Vietnam. He has advised his clients on various issues regarding the Pharmaceutical & Healthcare industry.

Lanh Dang Thu Nga
Associate

Lanh Dang Thu Nga is an associate of YKVN. Nga specializes in licensing and labor as well as trade and commercial issues, which affect businesses in the healthcare and pharmaceutical industry.

Nga has years of experience working with government officials at the Drug Administration of Vietnam, the Ministry of Health, the Ministry of Industry and Trade, and other management authorities. Nga has participated in various deals involving foreign investment activities in Vietnam, ranging from the licensing process to the post-licensing stage for pharmaceutical clients, as well as assisting foreign investment enterprises during their on-going business and investment in Vietnam.

In addition, Nga also has experience in dealing with trade and commercial issues, including advising multi-national companies on Vietnamese trade regulations and laws pertaining to customs, import-export control, advertising, and other trade-related issues.

Ho Van Khanh
Pharmaceutical Expert

Khanh has been one of the most experienced members of the YKVN's Pharmaceuticals and Healthcare Practice. Khanh is specialized in a wide range of practice areas, including, from compliance and corporation issues of importing and manufacturing FIE of worldwide research-based pharmaceutical companies in Vietnam, to labor regulations which directly related to high-level managers and medical representative's positions. Khanh has presented her client in multiple dialogues with top management authority of pharmaceutical and healthcare authority in Vietnam, such as Drug Administration of Vietnam and the Ministry of Health, to discuss core issues of the clients' business.

With her exceptional understanding of the pharmaceutical industry, together with her deep legal knowledge of the pharmaceutical law and legal framework in Vietnam, she was the expert that all multinational pharmaceutical companies come to if they need legal advice about pharmaceutical business in Vietnam.

Nguyen Thi Phuoc Hang
Pharmaceutical Expert

Hang is one of the key managers of the YKVN's Healthcare and Pharmaceuticals Practice. She has experience in advising on legislative development policy (such as pharmaceutical law, decrees guiding pharmaceutical regulations, tender circulars, etc.), and advising global leading pharmaceutical companies and associations in Vietnam. She is actively involved in a number of advice on regulatory affairs and compliance for worldwide research-based pharmaceutical companies in Vietnam, especially, advice on strategic business models for drug importation and distribution to ensure compliance with changing legislations.

Hang is regarded by Clients as a crisis-mitigation expert, a go-to lawyer for pharmaceutical related issues with her ability to analyze the Clients' issues with her complex understanding of the legislative system and the pharmaceutical industry.

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Established in 1999, YKVN has been recognized as the premier law firm in Vietnam and our excellence and expertise are acknowledged by fellow practitioners and by IFLR, Chambers and Partners, Asialaw and Legal 500 directories in which we are consistently listed as the top-tier firm. YKVN is the market leader in M&A, power and energy, capital markets, private equity, project finance, banking, healthcare & pharmaceuticals, real estate, domestic litigation and international arbitration of Vietnamese disputes.

YKVN's attorneys have been at the forefront of virtually all significant legal developments in Vietnam in the past 25 years. We have intimate knowledge of the Vietnamese legal, business, and political landscape. Our attorneys have handled the most complex matters at the highest levels. To ensure our top quality of work, we hire the best lawyers in Vietnam who are also trained and qualified in Vietnam, the U.S., UK, Australia, France and Singapore. Our attorneys have handled the most complex matters at the highest levels and are regularly ranked in the "First Tier" in various practices by major legal publications.

Most notably, YKVN has the most experienced team in healthcare & pharmaceuticals sector in the country. In our years of routinely involving with Vietnamese governmental agencies, our team has possessed a deep understanding of the authorities and industry, which enables us to capture the essence of the regulation and predict the progression of the pharmaceutical legislation. Our team is a team of capable, dedicated and diligent lawyers, who have years of experience advising demanding multinational pharmaceutical corporations at the international level. Our client bases include pharmaceutical association and various global pharmaceutical companies. We have provided our client wide a range of comprehensive legal services from advising on strategic legal framework for our clients' business model to compliance with labor law and the latest pharmaceutical legislation to ensure sustainable and successful long-term commercial partnership in Vietnam.