

# NEWSLETTER

## DECREE 155 – PHARMACISTS ARE NOW HCPS AND A NEW APPROACH TO DRUG INFORMATION PROVISION



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**R**ecently, the Vietnamese Government promulgated Decree No. 155/2018/ND-CP (Government, November 12, 2018), amending a number of regulations related to the conditions for business investment under the management of the Ministry of Health (“**Decree 155**”). **Decree 155 is an exciting piece of legislation**; most notably, Decree 155 explicitly provides that “pharmacy practitioners” are—like other medical practitioners—legally permitted to receive drug information from Medical Representatives. Not only does this revision to the law make the Import FIE far more commercially viable in Vietnam (a key objective of the pharmaceutical industry), but it also demonstrates that the MOH is willing to fix obvious omissions and errors in the legislative framework that will govern the pharmaceutical industry for the next several decades.

This newsletter—A Special Update—will discuss the new developments in Decree 155, and moreover, provide additional comments and analysis for your reference.

### **1. The critical role of pharmacists in Vietnam’s public healthcare system**

In Vietnam, as is the case in many countries with a less developed healthcare infrastructure, pharmacists are the most accessible health professionals for the public. Accordingly, they are useful resources for patients to obtain medical advice, including which medications treat particular ailments. In Vietnam, all research studies of patient care and treatment demonstrate pharmacists play a critical role and make a substantial contribution to the overall quality of healthcare by, among other measures, providing general medical advice, monitoring patient compliance with drug treatment regimes, detecting potential adverse drug reactions, and discussing an array of other issues important to both patients and Vietnam’s healthcare system. For example, and assuming the MOH could leverage their knowledge, Vietnamese pharmacists could become the most important aspect of an effective system to detect “adverse reactions” to medications. Fortunately, Decree 155 has formally recognized the importance of pharmacists in Vietnam.

### **2. The definition of pharmacist: Remains unclear**

Unfortunately (*or, perhaps, fortunately*), there is no legal definition for a “pharmacy practitioner” under Vietnamese law (a.k.a., a “pharmacist”). Accordingly, an important question arises; namely, are “intermediate pharmacists” or “assistant pharmacists” covered by Decree 155? This is a question that is not directly answered by the law and, therefore, companies are encouraged to seek legal advice and consider their tolerance for risk in this particular area of the law.

However, the Pharma Law, Article 2.36, provides that “pharmacy practice” means the application of a person’s expertise to pharmacy business and clinical pharmacology. Furthermore, “pharmacy business” means one, some or all stages of the investment process, including, *inter alia*, manufacture, sale, and provision of services related to drugs and medicinal ingredients on the market for/with an aim to make profit. Generally, a credible legal argument could be made that “pharmacists” are pharmacy practitioners who are “licensed” to perform pharmaceutical activities. However, there is room for more flexible definitions.

### **3. A new and reasonable approach**

In practice, patients receive the vast majority of their medical advice from pharmacists. Therefore, since pharmacists play an important role in the healthcare system—a role similar to medical practitioners—they must be included in the legally permissible scope of recipients of drug information from, for example, medical representatives.

Furthermore, the definition of drug information forum (i.e., pharmaceutical symposium) has also been amended to comply with the aforementioned amendments. For instance, Article 2.2 of Decree 54 has been amended as follows: “pharmaceutical symposium are introductory sessions on drugs or drug related scientific symposia intended for medical practitioners, *pharmacy practitioners*” (“*Hội thảo giới thiệu thuốc là buổi giới thiệu thuốc hoặc thảo luận chuyên đề liên quan đến thuốc cho người hành nghề y, dược*” in Vietnamese), (emphasis added).

As a consequence, eligible pharmaceutical business establishments / entities can provide drug information to pharmacists from the effective date of Decree 155 (i.e., November 12, 2018), as prescribed by law.

## **Conclusion**

In addition to ensuring an accurate supply of appropriate products, pharmacists' professional activities also cover counselling patients while dispensing prescribed and non-prescribed drugs. Pharmacists also play an important role in rural communities as shown, to take one example, by their participation in health-promotion programs.

By adding "pharmacy practitioners" within the scope of legally permissible "drug information recipients", the Vietnamese Government has officially recognized, and facilitated, the essential role of pharmacists in public healthcare promotion. Since November 12, 2018, pharmacists can legally receive drug information from medical representatives, which they can then legally share with their patients/customers. In sum, and in our view, this is an important step forward for the MOH and DAV. Not only did they recognize an important legislative omission that had the potential of causing harm to patient safety, but they fixed this omission—not with an official letter with questionable legality—but through a formal amendment of the law. Hopefully, this is simply one practical example of good things to come for both Vietnamese patients and the pharmaceutical industry.

*Please contact Eli Mazur (Founder and Managing Partner, YKVN's Pharma Practice Group) or Mr. Ngo Minh Hung, if you, your team, or your regional colleagues have any questions arising from this Newsletter. Eli and Mr. Hung can be reached in YKVN's Ho Chi Minh City Office, or by email (eli.mazur@ykvnlaw.com; hung.ngo@ykvnlaw.com).*

## 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. In 2018, Eli was recognized as a "Leading Lawyer" in Corporate and M&A by AsiaLaw, as well as the "Top Pharmaceutical Adviser" in Vietnam by panels at both Advisory Excellence and LinkedIn.

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.

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

In 2018, Hung was recognized as a "future star" by AsiaLaw of YKVN's Tier 1 Litigation & Arbitration Practice. Hung had the unique opportunity to serve as an intern at the Singapore International Arbitration Centre (SIAC), where he drafted briefs for arbitrators, prepared the arbitrators for dispute resolution, and, generally, sharpened his litigation and arbitration skills. Hung focuses on complex matters and has litigated cases in all levels of court and represented clients at arbitrations throughout Vietnam.

Hung also is a director of YKVN's elite Healthcare & Pharmaceutical Practice. With his critical reasoning, years of litigation experience, and commitment to handling complex matters in the healthcare and pharmaceutical sector, Hung has emerged as the go-to lawyer for Pharma MNCs for advice on issues ranging from compliance investigations, corporate matters, patent enforcement, and all types of litigation with a healthcare nexus.

Hung recently advised the founders of a pharmaceutical manufacturer in a dispute with a strategic investor, a large global pharmaceutical manufacturer with shares listed on the New York Stock Exchange (NYSE), regarding various claims, ranging from drug registrations to contractual misrepresentations.



**Nguyen Thi Thuy My**  
Associate

Ms. My is a key member and manager of YKVN's elite Healthcare and Pharmaceutical Practice. Ms. My is unique among Vietnamese lawyers, as her entire legal training and legal career has been dedicated to advising clients in the innovative pharmaceutical sector. After years of advising Pharma MNCs with operations in Vietnam, Ms. My has—not only built strong connections with clients—but also possesses a deep understanding of the industry, legal framework, and the central and provincial agencies and officials with the responsibility for interpreting and implementing the regulations. Ms. My's familiarity with the pharmaceutical industry enables her to capture (in her advice) the "essence" of regulations and give quality, practical, and value-added commercial advice to clients.

Ms. My remains the trusted counsel for several global leading Pharma MNCs with Vietnam operations, as well as the pharmaceutical association in Vietnam. She is an expert in advising on legislative developments and policy (such as the new pharmaceutical law, and implementing decrees, circulars, and official letters), and assisting clients to adjust business models, which maintain full legal compliance and optimize commercial results.



**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 advised Pharma MNCs operating in Vietnam on a broad array of matters ranging from corporate and employment to litigation and FCPA investigations and audits.

Besides a Juris Doctorate Degree from the United States (i.e., J.D.), Tung also has a Masters' Degree in Business Administration (i.e., M.B.A.). With his background, Tung has advised multinational pharmaceutical corporations on transactions, advising on cross-border business frameworks to optimize local operations in Vietnam, as well as several notable M&A deals in the healthcare sector. Tung always endeavors to utilize and leverage his business acumen, foreign legal training, and local network and understanding to give the most practical, and value-added, legal advice to clients.

Tung is highly regarded by Clients as a commercially-oriented and practical adviser with the ability to assist foreign clients in developing and maintaining short and long-term business and investment relationships with local partners in Vietnam.

Nga is an associate of YKVN, specializing in licensing and labor, as well as trade and commercial issues, which affect businesses in the healthcare and pharmaceutical sector.

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 regulatory authorities. Nga has participated in numerous transactions involving foreign investment activities in Vietnam with a particular expertise in licensing, which ranges from establishment-licensing and post-licensing to operations-licensing for pharmaceutical clients.

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

Khanh is the research and advising backbone of YKVN's elite Healthcare and Pharmaceutical Practice. Khanh is specialized in a few critical practice areas, including, compliance for research-based pharmaceutical companies in Vietnam, and labor & employment, which is critical for Pharma MNCs in Vietnam because of the odd circumstances surrounding the "housing" of medical representatives. Khanh has acted for clients in complex dialogue between management of pharmaceutical companies and regulators in Vietnam, such as the Drug Administration of Vietnam and the Ministry of Health.

With her exceptional understanding of the pharmaceutical industry, together with her deep legal knowledge of Vietnam's new pharmaceutical law and legal framework, Khanh has quickly become an expert trusted by Pharma MNCs—with their most sensitive commercial and operational information—to advise and act for in contentious matters.

Hang is a key manager, and, most importantly, leads the drafting team, in YKVN's elite Healthcare and Pharmaceutical Practice. She has experience advising on legislative developments and policy (such as the new pharmaceutical law, decrees guiding pharmaceutical regulations, tender circulars, etc.), and advising Pharma MNCs and the Pharma association in Vietnam on such legislative matters. She is actively involved in advising numerous Pharma MNCs in either adjusting or developing business models that comply with Vietnamese law, as well as models that mitigate risks (e.g., FCPA) that are at the forefront of concern for the local, regional, and global management of Pharma MNCs with operations in Vietnam.

Hang is regarded by clients as a go-to lawyer for pharmaceutical related issues, particularly with her ability to quickly analyze complex issues.



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After a five-year period serving as a branch office of the historic and global New York City law firm of White & Case, YKVN was established by its Founding Partners in 1999. YKVN quickly became recognized as a premier law firm in Vietnam by fellow practitioners and clients, as well as by peer-reviewed publications such as the IFLR, Chambers and Partners, Asialaw and the Legal 500. For two decades, YKVN has consistently been listed as a top-tier firm, and YKVN has repeatedly and consecutively been awarded “Law Firm of the Year” (e.g., every year from 2009 to 2017 by AsiaLaw). YKVN is the market leader in M&A, power and energy, capital markets, private equity, project finance, banking, healthcare & pharmaceuticals, corporate, real estate, and domestic litigation and international arbitration with a Vietnamese nexus.

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 the top quality of our work, we hire the best lawyers in Vietnam, who are trained and qualified by the best law schools 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 their practices by major legal publications.

Notably, YKVN has the most experienced team in healthcare & pharmaceuticals in Vietnam. In our half-decade representation of the Pharmaceutical association, our lawyers have routinely been involved in the most important and material dialogues with the Vietnamese Government on the important and pressing issues of the day for Pharma MNCs in Vietnam. Our Practice is comprised of a team of lawyers that possesses a deep understanding of the authorities and the industry, which enables us to make “educated predictions” about the progression, enforcement, and relevance of pharmaceutical legislation and implementing regulations. Our team is capable, dedicated and diligent, with years of experience advising Pharma MNCs on critical issues with demanding timelines and deadlines. Our clients include the pharmaceutical association of Vietnam and a majority of the largest global research-based pharmaceutical companies.