NEWSLETTER

DAV OFFICIAL LETTER 13439: A TALE OF TWO CITIES?

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YKVN

HANOI • HO CHI MINH • SINGAPORE

On July 13, 2018, the Drug Administration of Vietnam (the "**DAV**")—a department under the Ministry of Health ("**MOH**")—issued Official Letter No. 13439/QLD-PC ("**Official Letter 13439**") in response to six questions and proposals raised by Pharma Group—the Pharmaceutical Sector Committee of EuroCham in Vietnam ("**Pharma Group**")—relating to the following issues, among others: (i) the permitted activities of foreign-invested enterprises engaging in the importation of drugs into Vietnam ("**Import FIEs**"), as created and regulated by the 2016 Pharma Law and Decree 54; (ii) the permitted forms of cooperation between Import FIEs and their local distributors ("**Local Distributors**"); and (iii) the outsourcing of medical representatives (the "**MRs**"). Except for a small minority of issues, which did not receive adequate attention or responses from the DAV, in our view, Official Letter 13439 is a positive development on several fronts because it, generally, creates more "optionality" for multinational pharmaceutical companies ("**Pharma MNCs**") with operations in Vietnam, whether through an Import FIE, a representative office (an "**RO**"), or merely with drugs imported into, and circulating within, the Vietnamese market. Accordingly, in this newsletter we will discuss the DAV/MOH's core messages and intentions, which we derive from Official Letter 13439, as well as provide additional comments and analysis for your reference.

1. Possibility for Import FIEs to employ MRs prior to the CEPB

Official Letter 13439 has created legal ambiguity over the issue of whether Import FIEs of Pharma MNCs may employ MRs prior to obtaining a CEPB by creating additional grey area as follows:

First, while the possibility of hiring MRs prior to obtaining the GSP Certification/CEPB was squarely presented in Question 3.3 of the Pharma Group's proposal, the DAV/MOH chose not to answer this question. This creates the distinct possibility that regulators in different provinces will interpret the letter of the law in varying ways (i.e., a tale of two cities). For instance, just as the Service of Health ("**SOH**") in some provinces issued MR cards in the name of ROs for the past two decades—whereas other SOHs refused similar requests—there is a similar likelihood that SOHs in different provinces will permit, or not permit, Import FIEs to employ MRs prior to obtaining a CEPB.

Second, it appears that the DAV/MOH "consciously" did not want to address its view on this issue. Instead, the DAV/MOH may be waiting to make a decision on this issue after reviewing the Pharma Group's detailed roadmap and timeline on the proposed conversion from the RO model to the Import FIE model.

Pharma Group should present a detailed roadmap with specific timelines and corresponding actions.

Third, the DAV requested the Pharma Group to present a detailed roadmap with specific timelines and corresponding actions during the transition period. This request creates the possibility for the Pharma Group to propose and negotiate with the DAV/MOH, among other issues, hiring MRs once Import FIEs are established but prior to their GSP Certification and CEPB.

2. Coordination between Import FIEs and their Local Distributors

Unlike the stringent interpretation of Official Letter 473 dated January 18, 2018, Official Letter 13439 has created additional flexibility in the relationship between Import FIEs and their Local Distributors. Particularly, Official Letter 13439 stipulates that: "*Cooperation, discussion, and information sharing between Import FIE[s] and [their] Local Distributors must be ensured[, however] they [can] not [be] directly related to drug distribution activities of Local Distributors in Vietnam in compliance with Article 91 of Decree 54*".

The difference in language between these two official letters suggests that the DAV/MOH may be currently changing their point of view and are now willing to support and facilitate the commercial viability of Import FIEs to a far greater extent than originally regulated. So long as Import FIEs can ensure that their activities do not "interfere" with, "manipulate", or be characterized as "disguised distribution", then the DAV/MOH appears willing to permit Import FIEs to share information and make recommendations to their Local Distributors, including information and recommendations related to pricing, tenders, distribution strategies, and the development of drug supply plans.

3. Field Force Agreements—A new home for MRs

Since the promulgation of the 2016 Pharma Law, which put an end to the possibility of hiring MRs by the ROs of Pharma MNCs, Pharma MNCs have been ensconced in legal uncertainty about housing their MRs. Fortunately, Pharma MNCs can find a place of refuge in Official Letter 13439, which is unprecedented in its acknowledgement and awareness of agreements entered into between Import FIEs and their Local Distributors committing the MRs of Local Distributors to work exclusively on the drugs of the respective Import FIE ("**Field Force Agreements**").

At the moment, while not many Pharma MNCs have a legal presence in Vietnam (i.e., an Import FIE), Field Force Agreements have traditionally been signed between the [offshore] Pharma MNCs and their Local Distributors in Vietnam. The language in Official Letter 13439 gives rise to the inference that the DAV/MOH would endorse the above mechanism, rather than continuing to allow ROs of Pharma MNCs to directly employ MRs (particularly, pursuant to Circular 07, after the expiration of MR cards, which are issued in the name of ROs of Pharma MNCs).

Having said that, although the current Field Force Agreements between [offshore] Pharma MNCs and Local Distributors are somehow recognized by the DAV/MOH, this is not a sustainable model and contains certain risks, which must be taken into full consideration for the following reasons:

First, in Official Letter 13439 as well as Circular 07, the DAV/MOH's intention is clear: to make Import FIEs the new home for MRs, since, among other things, that would show the long-term commitment of Pharma MNCs to a business plan/model in Vietnam.

The DAV/MOH for the first time acknowledges Field Force Agreements.

Second, when using outsourced MRs dedicated to their respective drugs, the Pharma MNCs will need to take into account their exposure to FCPA risks (i.e., the misconduct of Local Distributors' MRs when carrying out drug information activitites).

Experience has shown that Local Distributors are far more comfortable mitigating *their local labor risks* and allowing the Pharma MNCs to *assume the global FCPA risks* by entering into "voluntary termination agreements", which include severance packages (and, which, the U.S. SEC, may interpret as rewarding employees for FCPA violations). Accordingly, the only real solution to this problem of incentives, is housing MRs within Import FIEs of Pharma MNCs, which are willing to assume the local labor risks in order to mitigate their global FCPA risks.

Conclusion

While some questions remain unanswered or receive inadequate attention, Official Letter 13439 has provided us invaluable understanding about the views and intentions of the DAV/MOH, which are unmistakably helpful for Pharma MNCs in planning their business models in the years to come. Particularly, the grey areas created by Official Letter 13439 open "wiggle room" for the Pharma MNCs to negotiate with the DAV/MOH on the transition period, by requiring the Pharma Group to submit a detailed roadmap for the conversion from ROs to Import FIEs. Moreover, the DAV/MOH's recognition of Field Force Agreements and the the consistent references to Import FIEs show that **the shift from the current RO model to an Import FIE is inevitable**. Accordingly, we recommend the Pharma MNCs work closely with the Pharma Group to build a detailed roadmap, and, in parallel, to observe the market for further guiding regulations and relevant official letters from the DAV/MOH to clarify Import FIEs' permitted and prohibited activities.

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@ykvn-law.com; hung.ngo@ykvn-law.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.

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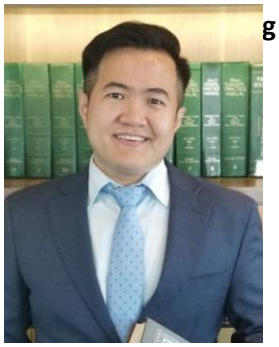
In 2018, Hung was recognized as a "future star" by AsiaLaw of YKVN's Tier 1 Litigation & Arbitration Practice. Hung had the unique opportunity to serve as an intern at the Singapore International Arbitration Centre (SIAC), where he drafted briefs for arbitrators, prepared the arbitrators for dispute 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 multinational pharmaceutical corporations ("**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.



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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.

Nguyen 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.

Lanh Thu Nga
Associate

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.

Ho Van Khanh
Pharmaceutical Expert

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.

Nguyen Phuoc Hang
Pharmaceutical Expert

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.