NEWSLETTER

NEW CIRCULAR ON GSP FOR DRUGS AND DRUGS MATERIALS

Monthly Update (April 2019)

YKVN

HANOI • HO CHI MINH • SINGAPORE

Storage of drugs/drug materials is an important process to ensure and maintain the safety and quality of drugs/drug materials for production or distribution. In addition to "Good Storage Practices" ("**GSP**") promulgated by the World Health Organization (WHO), each country or community has its own set of principles and standards on storage of drugs and drug materials to ensure and maintain the safety and quality control throughout process of storing drugs/drug materials. In Vietnam, on January 10, 2019, the new Circular No. 36/2018/TT-BYT regulating GSP on drugs and drug materials took effect ("**Circular 36**"), and replaced Decision No. 2701/2001/QD-BYT dated June 29, 2001 after nearly two decades of application.

Through this Newsletter, we aim to highlight key issues in Circular 36, which include: (i) confirmation that foreign-invested enterprises importing drugs into Vietnam ("**Import FIE**") are subject to GSP requirements; (ii) the process for the GSP conformity assessment; and (iii) additional technical issues for a GSP-qualified warehouse. Our hope is to convey a better understanding of the technical requirements applicable to GSP-qualified warehouses of Import FIEs established in Vietnam by multinational pharmaceutical companies ("**Pharma MNCs**").

1. Import FIEs – One of the GSP Certification Holders

Import FIEs are one of the entities capable of being a GSP Certification Holder.

Circular 36 now counts the following amid the subjects of GSP Certification: importers, including Import FIEs, exporters, and storage service providers (collectively, the "**storage establishments**").

That said, Import FIEs, among other entities, are required to comply with GSP regulations, and hence, GSP Certification will be the evidence of their compliance. Indeed, GSP Certification is a condition precedent for issuance of the Certification of Eligibility for Pharmaceutical Business ("**CEPB**"), which an Import FIE needs in order to fully operationalize its commercial business in Vietnam.

Pursuant to a few official letters and our recent discussions with the Ministry of Health/Drug Administration of Vietnam ("**MOH/DAV**"), an Import FIE must itself operate and manage the warehouse, whether such warehouse is built by the Import FIE or leased from a third party. As a result, it is clear that Import FIEs must be named in the GSP Certification (and CEPB later on).

2. Procedures for GSP Conformity Assessment

Procedures for the issuance of GSP Certification, as well as the competent regulatory authority in Circular 36, have been changed. More precisely, the storage establishments only need to prepare one single application for the issuance of both GSP Certification and the CEPB, instead of separate applications as provided previously. Notably, the DAV—the issuance authority under Circular 36—will not automatically issue the GSP Certification to storage establishments, unless such storage establishments clearly state their request to be granted GSP Certification in the application dossier.

Single application for obtaining both GSP Certification and CEPB.

According to Circular 36, the process for issuance of GSP Certification basically comprises the following steps:

- *Step 1*: Establishment of the assessment team and estimation of the onsite check within 5 days from the date of the receipt of an adequate dossier.

  In parallel, the foregoing information will be notified to the storage establishment.

- *Step 2*: Onsite inspection by the assessment team at the warehouse of the storage establishment within 15 days from the notification date.

  Consequently, the assessment minutes will be signed between the assessment team and the storage establishment.

- *Step 3*: For any storage establishments touching Level 1 – No deficiencies and no

serious deficiencies, within 10 days from the signing date of the assessment minutes, the DAV's submission will be sent to the Health Minister for the issuance of the CEPB and the 3-year GSP Certification (if the storage establishment has requested to be issued the GSP Certification in its application).

For any storage establishments touching Level 2 – No serious deficiencies, but some deficiencies, within 5 days from the signing date of the assessment minutes, the assessment team will send them GSP assessment report(s) for their correction.

For any storage establishments touching Level 3 – Serious deficiencies, the storage establishment shall receive a written notification of the GSP non-conformity status attached to the assessment report. As a result, such storage establishment will be issued neither the CEPB nor GSP Certification.

- *Step 4*: Within 5 days from the issuance date of CEPB, the DAV and MOH must publish on their websites certain information of the storage establishment being issued with the CEPB.

3. Technical Issues for a GSP-qualified Warehouse

To satisfy the GSP requirements provided in Circular 36, storage establishments should take into account the following issues:

a. Human resources

A warehouse must have the following positions, among others: (i) warehouse manager ("*thủ kho*" in Vietnamese); (ii) the person in charge of pharmacy expertise ("*người chịu trách nhiệm chuyên môn về dược*" in Vietnamese); (iii) head of quality control ("**QC Head**").

Per our verbal consultation with the DAV recently, among the foregoing statutory positions, the person in charge of pharmacy expertise must be the employee of the storage establishment, whereas the warehouse keeper and QC Head can be outsourced.

In our view, the Warehouse manager, Person in charge of pharmacy expertise, QC Head should be employed by the storage

We, however, have a different view – that they should be employed by the storage establishments.

Given that those positions are the heart of a warehouse, particularly: (i) the warehouse manager is in charge of warehouse booking, inputs and outputs, etc.; (ii) the person in charge of pharmacy expertise plays a key role in ensuring the compliance of GSP standards; and (iii) the QC Head is responsible for quality control of drugs/drug materials stored at such warehouse, those personnel should be employees of the storage establishment (e.g., the Import FIEs).

b. Regulatory facilities

The storage establishment must ensure that its warehouse is equipped with full facilities. Appropriate vehicles and equipment for storing drugs/drug materials should be available in place (e.g. ventilation fans, air-conditioning thermometers, trucks, forklifts, hygrometers, cold rooms, refrigerators, vaccine vial monitors, freeze tags, etc.).

Per our verbal discussion with the DAV, the equipment must be separate and is not permitted to be shared with any other parties. As the Import FIE cannot carry out drug transportation activities, the requirement on trucks may not be applicable.

c. Full functional areas

The storage establishment must be large enough to be allocated with full functional areas of a warehouse as provided in Circular 36, including, among others: drug-in/drug-out area; quality control; storage; packaging and labeling area; fitting room; office of the warehouse.

Per our verbal discussion with the DAV, these functional areas must be separate and are not permitted to be shared with any other parties. This provision prohibits a storage establishment from using the same functional areas (e.g., fire and fighting, air-conditioning area) in case if such storage establishment shares a specific warehouse with the other parties in the same warehouse complex.

4. Additional Discussions

a. Periodic GSP assessment

Please note that periodic GSP assessment shall take place every 3 years from the date of the completion of the preceding assessment (exclusive of any ad-hoc assessment, if any).

The DAV's online announcement of periodic GSP assessment on the storage establishment in the successive year comes annually in November.

b. Changes required for amending GSP Certification and CEPB

Between each periodic GSP assessment, the storage establishment can apply for an amendment to the GSP Certification in the following cases:

(i) Changes in warehousing area; or addition of warehouse(s) in the new area, at the same place of business; or

(ii) Extension of a warehouse; repair to or change in structure and layout of the warehouse; or changes in the ancillary system, design principles, or utility operating system that cause impacts to storage conditions as well as storage requirements.

Under circumstances of (i), the DAV will conduct an onsite inspection at the storage establishment, while for scenario of (ii), the DAV will evaluate whether the storage establishment has satisfied GSP standards by reviewing its documentation. Please note that in the circumstances of (ii), if the storage establishment fails to meet GSP standards, and subsequently, fails to submit on time a satisfactory remedial action report thereof, the competent agency will conduct an ad-hoc onsite inspection with respect to such storage establishment.

c. Obtaining new CEPB

Notably, a storage establishment will be required to obtain a new CEPB if there is any change in the type of pharmaceutical business establishment such as change(s) in the scope of pharmaceutical business causing the change in applicable conditions, or change(s) in the business location. The process is similar to the procedures presented in Section 2 as previously discussed.

5. Conclusion

Circular 36 focuses not only on the process of obtaining the GSP Certification/CEPB, but also on various technical issues related to warehouses. From our experience in the Vietnamese pharmaceutical industry, the MOH, by highlighting the detailed procedure of the GSP conformity assessment and recognizing Import FIEs as eligible GSP Certification holders, has been taking steps to furnish ideal conditions for the playground of Import FIEs in Vietnam. This is a good signal for Pharma MNCs to extend business in Vietnam, through establishing Import FIEs and activating its import rights.

Please contact Eli Mazur (Founder and Managing Partner, YKVN's Pharma Practice Group) or Ms. MY, if you, your team, or your regional colleagues have any questions arising from this Newsletter. Eli and Ms. MY can be reached in YKVN's Ho Chi Minh City Office, or by email (eli.mazur@ykvn-law.com; my.nguyen@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.

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.

Lanh Dang 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 Thi Van Khanh
Associate

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 Thi Phuoc Hang
Associate

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.