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NEWSLETTER

DRUG PROCUREMENT UNDER CURRENT VIETNAMESE REGULATIONS AND THE EU-VN-FTA

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Industry Report by YKVN's Life-Sciences Practice Group

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With a fast growing population, Vietnam is a boomtown with high demand for quality pharmaceutical products.

The days of Vietnamese going abroad for simple surgeries has ended, caused by the travel restrictions under Covid-19 regulations, but most importantly, Vietnam has some excellent doctors, surgeons, hospitals, technology, and—most importantly—perhaps "medical tourism" is no longer an absolute necessity. Vietnam shines again, during the Covid-19 Pandemic.

It may be time for Big Pharma MNCs to begin considering Vietnam as a credible market—with competent talent and competitive labor and land costs—as a place to manufacture, toll or otherwise, some of their pharmaceutical products. The Big Pharma MNC that moves first will surely be rewarded by the MOH, DAV and other regulatory bodies.

As we know, drug price controls are one of the main tools of the Government to manage national healthcare expenditures, and, indeed, incentivizing the production of drugs locally could be yet another tool.

A few Big Pharma MNC's have realized this and, therefore, use local manufacturers in the final stages of drug production. Despite the growing demand and technical competence, domestic production of needed drugs is still nascent due to low foreign and domestic investment in either production or R&D activities.

Vietnam remains largely reliant on imported drugs, particularly on high technology products, as well as active pharmaceutical ingredients ("**API**") produced offshore.

Thus, the new tender circular has included drug production standards in order to ensure that healthcare facilities can procure high quality drugs with reasonable prices.

More specifically, on July 11, 2019, Vietnam's Ministry of Health ("**MOH**") issued Circular No. 15/2019/TT-BYT providing regulations on drug tenders applicable to public healthcare facilities ("**Circular 15**"), which superseded all previous regulations (under Circular No. 11/2016/TT-BYT) and took effect from October 1, 2019.

Circular 15 has classified generic tender packages into 5 specific sub-packages based on the drug-manufacturing standards, pursuant to which, generic packages 1 and 2 (respectively, "**Gx1**" and "**Gx2**") are two of the most popular tender packages in Vietnam.

This newsletter provides a brief overview of the mandatory standards of producing Gx1 and Gx2 drugs, and Vietnam's tender regulations governing these packages, with a short discussion on the impact of the European Union Vietnam Free Trade Agreement ("**EU-VN FTA**") on Vietnam's pharmaceutical market.

I. DRUG CLASSIFICATION

1. Gx1

Pursuant to Circular 15, Gx1 includes drugs that meet one of the following requirements:

a) ***Drugs manufactured entirely by production lines satisfying EU-GMP standards or equivalent EU-GMP standards in a country under the list of Stringent Regulatory Agencies ("SRA").*** It can be understood that the manufacturing facilities along with the quality of their production line shall meet the EU-GMP standards set out by the European Medicines Agency ("**EMA**") (hereinafter referred to as "**EU-GMP Certificate**"). To be granted with an EU-GMP Certificate, the manufacturing facilities must be examined by the competent authority of an EMA country in accordance with the specific conditions and procedures regulated by such relevant country. As noted, EU-GMP standards do not require the drugs to be entirely manufactured in the EMA country. Rather, drugs which can be produced in the SRA countries (e.g., the United States, Japan, the United Kingdom, Canada, etc.) with the equivalent EU-GMP standards shall be classified as Gx1 drugs.

b) ***Drugs which are on the list of brand-name drugs or biologicals as declared by the MOH (except for brand-name drugs under the list of drugs eligible for price negotiation issued by the MOH and were announced price negotiation results).*** The drug owner must submit an application to the MOH requesting to use a drug as a brand-name drug. The drug subject to a brand-name drug declaration (except biologicals) shall be specified in the application for obtaining marketing authorization ("**MA**") and satisfy the following criteria: (i) the safety and efficacy data are sufficient; and (ii) the drug is approved for free sale by the competent authorities, except for new drugs manufactured in Vietnam. Currently, the law is silent on the timeline for making this declaration procedure; however, it would likely be concurrently conducted with the competent authority's review of the MA application. As a matter of practice, it may be a time-consuming process (e.g., 6 months to 1 year) for a requested drug to be officially declared, as the MOH/DAV will gather a number of declared drugs and include them into one decision. Thus, drugs under this procedure may be delayed in participating in tenders.

c) Drugs are manufactured entirely in Vietnam and satisfy all requirements as follow:

- Drugs are (aa) manufactured entirely by a production line satisfying EU-GMP standards or equivalent EU-GMP standards (see section II.1(a) above for details); and then (bb) being certified to satisfy EU-GMP standards or equivalent EU-GMP standards by the competent authority in Vietnam. Particularly, the production line will be re-examined by the Vietnamese competent authority in order to be confirmed as an EU-GMP-standards satisfied drug;

- Drugs are granted the MAs by the competent authority of a SRA country; and

- Drugs sold in Vietnam and drugs that are granted the MAs by the competent authority of a SRA country shall (x) have the same dosage form, production process, quality standards, verification method, and (y) have their active ingredients, excipients with the same quality standards, manufacturing site and place of production.

In particular, the foregoing information shall be declared in a pro-forma form as annexed to Circular 15. Apart from such declaration form, and as a matter of practice, the procuring entity may, at its own discretion, request for supporting documents. Although the manufacturer may support providing production details, the bidder shall eventually be responsible for all information indicated in both declaration form and the supporting documents for the purpose of the tender.

2. Gx2

Under Circular 15, drugs classified in Gx2 are required to satisfy one of the following conditions:

a) Drugs are entirely manufactured by a production line (i) satisfying EU-GMP standards or equivalent EU-GMP standards, and (ii) being certified to satisfy EU-GMP standards or equivalent EU-GMP standards by the competent authority of Vietnam (see sections I.1a) and I.1c) for details).

b) Drugs are entirely manufactured by a production line in a country being a member of the Pharmaceutical Inspection Co-operation Scheme ("**PIC/s**") and the International Conference on Harmonization ("**ICH**") (e.g., Austria, Denmark, Netherlands, Poland, Sweden, Japan). The production line has been granted PIC/s-GMP certificates by the competent authority of such country first and then re-examined by the Vietnamese authority to obtain certificate of satisfaction of the PIC/s-GMP.

- Different than section (a) above, drugs under this condition shall be produced in certain nations being members of PIC/s and ICH. The examination and relevant procedures for PIC/s-GMP inspection will be conducted by these member states. If the manufacturing site satisfies the standards, it will be granted with a PIC/s-GMP certificate. Yet, upon obtaining a PIC/s-GMP Certificate, the production line will be re-examined by the Vietnamese competent authority in order to be confirmed as a PIC/s-GMP-standards satisfied drug.

- Notably, in case many manufacturers get involved in the manufacturing process of the tendering drugs, all manufacturers must meet the above conditions to join the bidding in Gx2.

II. TENDERING REGULATIONS APPLICABLE TO Gx1 AND Gx2

1. Tender Submission

According to Circular 15, a bidder can submit a bid for one or more packages if its drugs satisfy the criterion of such package, provided that the bidding price of the same drug is consistent in all categories in which it is participating.

For instance, bidders with drugs in Gx1 may submit the widest range of packages, which include Gx1, Gx2 and Gx5. To this extent, generics classified in package 5 (i.e., Gx5) include drugs manufactured by a production line satisfying the WHO-GMP requirements and have been granted certificates by the competent authorities of Vietnam, but they are not classified in other packages. With a narrower scope, bidders with Gx2 drugs may only submit Gx2 and/or Gx5 tender packages.

Notwithstanding, in relation to drugs in Gx2, it is worth noting that the procuring entity must clearly indicate in the bidding documents or the proposal requests that the bidder must not offer imported drugs in Gx2 if the procurement is applicable to drugs that satisfies the EU-GMP standards and are included on the List of Domestically Manufactured Drugs Satisfying Treatment, Pricing and Supply Requirements issued by the MOH (as listed in Circular 03/2019/TT-BYT).

2. Tender Offer

Circular No. 15/2020/TT-BYT has been issued by the MOH on August 10, 2020 (effect on October 6, 2020) to promulgate the list of drugs procured through bidding, list of drugs procured through centralized bidding, list of drugs procured through price negotiation ("**Circular 15/2020**"), in which the criteria for compiling the list of drugs procured through different means are provided.

According to provisions therein, the brand-name drugs shall only be procured under the form of a price negotiation; whereas generic drugs may be purchased (i) by bidding through either the National Centralized Drug Procurement Center ("**NCDPC**") or local centralized bidding governed by the NCDPC if the drugs are under the list of drugs procured through centralized bidding, or (ii) by drug tender organized by the healthcare facilities if the drugs are only included in the list of drugs procured through bidding but not subject to centralized bidding.

As such, in case a specific generic drug is included in the list of drugs procured through centralized bidding, the healthcare facility, according to its need, will propose the procurement to the centralized drug procurement unit in order for such unit to consolidate drug proposals from facilities and conduct the centralized bidding procedure.

For drug bidding conducted by healthcare facilities, before opening a drug tender, the procuring healthcare facility must prepare, appraise and approve the bidding documents or proposal request which shall be made in compliance with both regulations on bidding in general and specifications for drug tender.

Notwithstanding the foregoing, by issuing the Resolution No. 59/NQ-CP dated July 7, 2016, the Government of Vietnam has assigned the Social Security of Vietnam (VSS) to carry out a pilot national bidding for drugs, including, among others, brand-name and generic drugs, in the form of concentrated procurement from January 1, 2018. To this date, the concentrated procurement was conducted twice with promising goal to reduce the awarded drug price.

3. Estimated Price

Under Circular 15, the estimated price of Gx1 drugs shall not be higher than prices of brand-name drugs or reference biologicals having the same active ingredients, concentrations or contents, dosage form specified in contractor selection plans of healthcare facility. The estimated price of Gx2 drugs with the same active ingredients, concentrations or contents, dosage form specified in contractor selection plan of healthcare facility shall not be higher than the estimated price of brand-name drugs or reference biological and Gx1.

III. IMPACT OF THE EU-VN FTA ON PHARMACEUTICALS PROCUREMENTS

The European Union Vietnam Free Trade Agreement ("**EU-VN FTA**") officially entered into force on August 1, 2020 sets a number of new measures towards the customs and conditions to trade between the EU and Vietnam for various goods and services (including drugs and medical devices).

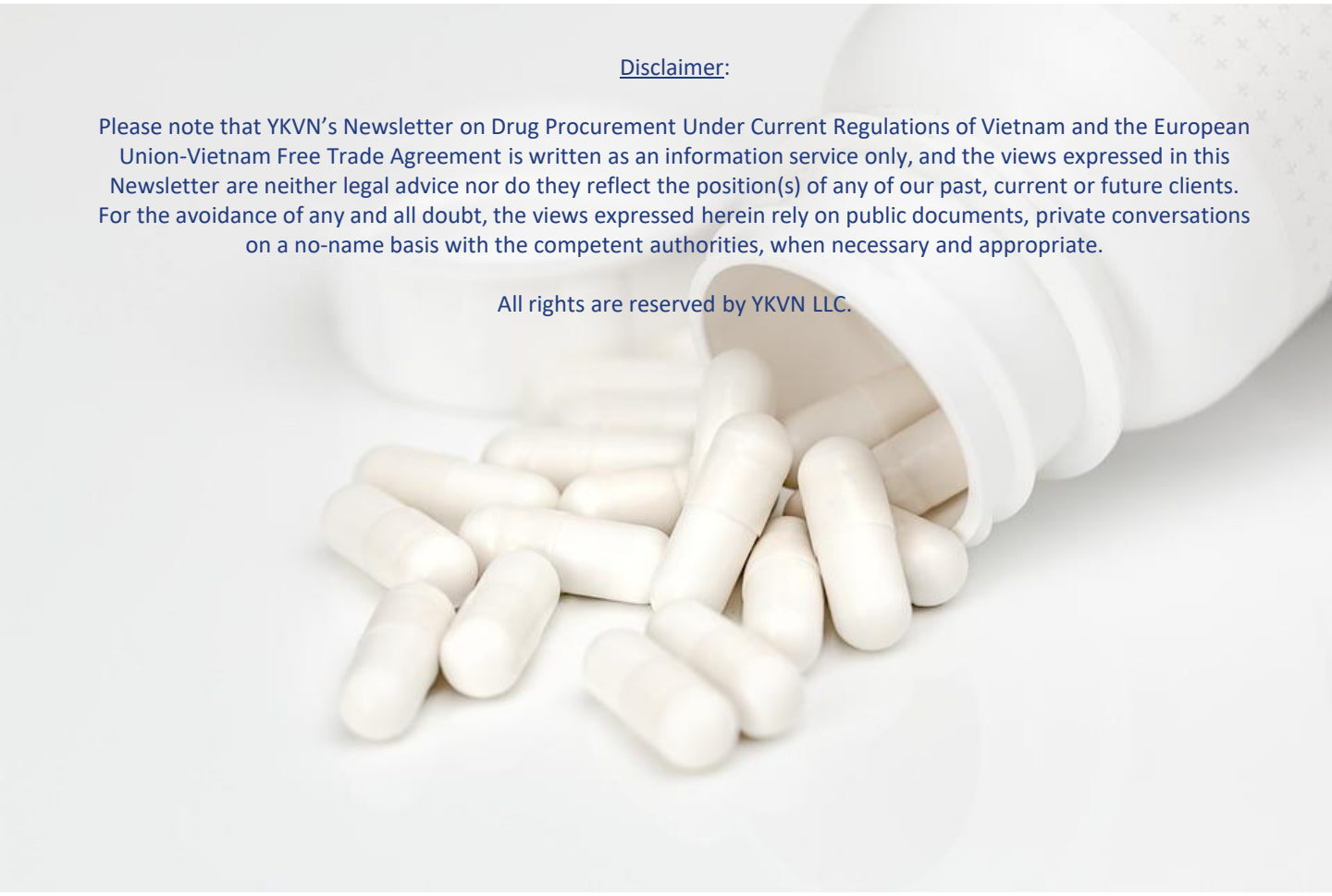
In one of its most remarkable improvements to current regulations, the EU-VN FTA for the first time allows foreign entities (i.e., European companies) to attend tenders for public procurement in Vietnam. In this regard, the parties to the EU-VN FTA agree that the conditions to bid for pharmaceutical procurement will not be less favorable for the EU companies than the ones applicable for Vietnamese entities. Furthermore, two years after the effective date, the NCDPC (the procurement entity authorized by the MOH and the provincial departments of health of Vietnam) will benefit from the direct purchase of drugs from the European suppliers via public procurement, provided that the thresholds set forth in the EU-VN FTA are complied with fully.

Accordingly, the share of bids originating from Vietnamese companies is predicted to decline from 100% to only 65% after two years of entry into force of the EU-VN FTA of total pharmaceutical procurement bids in Vietnam. Nevertheless, with a relatively long period for complete market liberalization (from 5 to 16 years), Vietnamese domestic enterprises will have time to sufficiently prepare themselves for the upcoming challenges caused by rapid market entry of EU suppliers/contractors.

Also, thanks to the EU-VN FTA, Vietnamese pharmaceutical companies are now allowed to bid in the EU pharmaceutical procurement market. To ensure a full transparency and promote the bids between the EU and Vietnam, public procurement will be fully accessible on a dedicated website.

This Newsletter offers a glance at the classification and rules of Gx1 and Gx2 tender packages under current regulations, with a discussion of the EU-VN FTA's impact on the pharmaceutical market of Vietnam. We hope the information contained in our newsletter is helpful for multinational pharmaceutical companies in general and for EU drug suppliers in particular, who would like to invest in drug manufacturing/import in Vietnam, the classification and participation of Gx1 and Gx2 drug distributors in tender process, and direct market access thereafter.

If your company requires any additional information, we will be delighted to assist your local and regional teams in navigating through the complex regulatory framework of Vietnam's pharmaceutical industry and to offer strategic approaches to achieve the most desirable outcome.



Disclaimer:

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