Indochine Counsel
Business Law Practitioners

ClientAlert

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Introduction

Dear Reader,

This month saw a handful of new regulations that affect business in Vietnam. We've briefed them and outlined the most important changes from each new regulation. They cover numerous topics including public private partnerships, origin of goods, commodities exchanges and pharmaceutical labeling.

As always we hope you find this month's Client Alert helpful and wish you prosperity in your dealings. We look forward to working with you.

Kind regards,
Indochine Counsel

In this issue

Investment in the form of Publice-Private Partnership

On 4 May 2018 the Government issued Decree No. 63/2018/ND-CP on investment in the form of public-private partnership ("**Decree 63**"). Decree 63, in place of Decree No. 15/2015/ND-CP governing the same contents ("**Decree 15**"), is expected to make a positive impact on the public-private partnership sector.

Public-private partnership investment ("**PPP Investment**") is implemented based on contractual agreements in the following basic forms:

- Build – Operate – Transfer contract (commonly known as BOT contract)
- Build – Transfer – Operate contract (commonly known as BTO contract)
- Build – Transfer contract (commonly known as BT contract)
- Build – Own – Operate contract (commonly known as BOO contract)
- Build – Transfer – Lease contract (commonly known as BTL contract)
- Build – Lease – Transfer contract (commonly known as BLT contract)
- Operation – Management contract (commonly known as O&M contract)

Forms of contracts that mix and match the listed forms above or other kinds of contract approved by competent authority can also be used as the basis of PPP Investment.

A new equity capital rate contributed by the investor has been applied as of the effective date of Decree 63, particularly as follows:

- Where total investment capital does not exceed VND1,500 billion, the equity capital contributed by the investor must not be lower than 20% of the total investment capital.
- Where the total investment capital exceeds VND1,500 billion, the equity capital rate shall be determined based on the percentage of the rate, for example, the part of the investment less than VND1,500 billion the investor must contribute 20% of the capital, the part above VND1,500 billion must include 10% from the investor.

In comparison with Decree 15, Decree 63 provides more detail and clear provisions in respect of procedures for the implementation of the PPP Investment in general and the decision on investment policies in particular. Accordingly, the authority of the government bodies (i.e. National Assembly, Prime Minister, Ministers and local authorities) regarding the decision on investment policies for the PPP Investment has been clearly clarified.

General procedures for the implementation of the PPP Investment shall be as follows:

- Step 1: Preparation and evaluation of pre-feasibility study report
- Step 2: Approval on decision on investment policies and announcement of the project
- Step 3: Preparation, evaluation and approval of feasibility study report
- Step 4: Selection of the investor(s)

- Step 5: Negotiation, establishment of enterprise implementing project (if any) and execution of contract of the project
- Step 6: Implementation of the project
- Step 7: Final settlement and transfer of the project

The PPP Investment project pertaining to the application of high-end technologies and projects conducted on the basis of BT contract shall comply with separate procedures as specified in detail in Decree 63.

Decree 15 also covered brief procedures for the transformation of the project from public investment project to the PPP Investment project.

The implementation of the PPP Investment in compliance with its investment registration certificate issued prior to the effective date of Decree 63 shall remain unchanged. In case of any amendments, the parties of the project shall only be required to revise the contract of the project for the due compliance with Decree 63 and relevant prevailing laws.

Decree 63 took effect on 19 June 2018 and replaced Decree 15 and several provisions regarding investment policies and the PPP Investment decisions stated in Decree 136/2015/ND-CP, dated 25 December 2015, on guidelines of some provisions of the Law on Public Investment.

Origin of goods

On 3 April 2018 the Ministry of Industry and Trade of Vietnam (the "**MOIT**") issued Circular 5/2018/TT-BCT ("**Circular 5**") on the origin of goods. Circular 5 provides new regulations on identifying origin of exported goods and imported goods, which are considered as a guideline for Decree No. 31/2018/ND-CP of the Government, dated 8 March 2018, detailing the Law on foreign trade management in terms of origin of goods ("**Decree 31**").

Goods of which the origin are identified under Circular 5 are goods originating in a country, group of countries, or territory where the last processing operation is performed that substantially transforms such goods.

The preferential rules for identifying the origin of goods are stated under Circular 5 as follows:

- The identification of origin of imported and exported goods which are subject to tariff or non-tariff preferences shall comply with treaties to which Vietnam is a signatory or Vietnam acceded as a member and relevant legal documents on guidelines for the implementation of these treaties.
- The identification of origin of exported goods which are subject to general tariff preferences and other unilateral preferences shall comply with the regulations of the importing countries regarding these preferences and regulations of the MOIT on guidelines for such rules of origin.

Meanwhile, the non-preferential rules for identifying the origin of goods are regulated as follows:

- Exported / imported goods shall be treated as wholly produced or obtained in a country, group of countries, or territory if they comply with Article 7 of Decree 31.
- Exported / imported goods shall be treated as not wholly obtained or produced in a country, group of countries, or territory if they satisfy the criteria prescribed in Appendix I of Product Specific Rules issued together with Circular 5 on guidelines for Decree 31, which are standard of "*Change in tariff classification"* and standard of "*Local value content".*

In addition, traders requesting for issuance of the Certificate of Origin must declare and commit that the origin of goods to be exported meets the criteria in relation to the preferential rules or non-preferential rules under the forms as attached in Appendices of Circular 5.

Circular 5 took effect on 3 April 2018.

Origin of goods part II

On 8 March 2018 the Government issued Decree No. 31/2018/ND-CP providing detailed regulations on the Law on Foreign Trade Management regarding origin of goods ("**Decree 31**"), which took effect immediately on its date of issue and repeals Decree No. 19/2006/ND-CP providing the same contents of the Government ("**Decree 19**").

Decree 31 regulates categories of "originating goods", "goods with a pure origin" and "goods with multiple countries of origin".

The traders who apply for the Certificate of origin of goods ("**C/O**") for the first time must register their files with the agency issuing C/O directly or via the system on management and issuance of electronic C/O at www.ecosys.gov (or another website as instructed). The trader's files must be updated in case of any changes or even if there are no changes, once every two (2) years.

In comparison with the regulations under Decree 19, the application files for issuance of the C/O as stated in Decree 31 shall comprise more documents to be declared. Accordingly, a full application file for issuance of the C/O shall include the followings:

(a) Fully and validly declared application for issuance of a C/O (standard form);

(b) Fully declared standard form for the corresponding C/O;

(c) Hard copy customs export declaration, unless the law does not require a customs declaration for the export goods;

(d) Copy commercial invoice (sealed by the trader as a true copy from the original);

(e) Copy bill of lading or equivalent transport document (sealed by the trader as a true copy from the original);

(f) Detailed list of export goods satisfying the preferential origin criteria or the non-preferential origin criteria on the standard form stipulated by the MOIT;

(g) Declaration of origin by the producer or supplier of originating materials or of originating materials produced domestically (where such materials are used for the next stage in order to produce other goods);

(h) Copy of the goods production process/rules (sealed by the trader as a true copy from the original);

(i) In necessary cases, the C/O-issuing authority may conduct an actual on-site inspection of the production establishment of the trader; or may require the trader applying for issuance of the C/O to lodge additional copy vouchers (sealed by the trader as true copies from the originals).

Trading through commodity exchange

On 9 April 2018 the Government issued Decree No. 51/2018/ND-CP ("**Decree 51**") providing regulations on amending and supplementing a number of articles in Decree No. 158/2006/ND-CP stipulating the Commercial Law on trading through the commodity exchange (the "**CE**").

The notable regulations under Decree 51 are requirements on establishment of the CE. Accordingly, the CE shall be established if it complies with the following requirements:

(i) It has charter capital of at least VND150billion;

(ii) It has an information system that meets requirements for technology for trading in commodities through the CE. In particular:

- The server system shall operate stably and there should be at least one backup server at the ready in the event of a failure of the primary server;
- The server system shall back up business application data, trading data and recover data in the event of a failure;
- Application software shall comply with requirements for intellectual property rights in accordance with regulations of law;
- The software system shall have the ability to log trading, payment and delivery during

business process for a period of at least 5 years;

- The information system shall comply with technical regulation on cyber information security, if any.

In comparison with the previous regulations, Decree 51 removes the requirements on qualification, experience and capacity of the Director/ General Director when establishing the CE.

Decree 51 took effect on 1 June 2018.

Labeling of drugs, drug materials and package inserts of drugs under the new circular

The Ministry of Health (the "**MOH**") issued Circular No. 1/2018/TT-BYT, on 8 January 2018, regulating the labeling of drugs, drug materials and package inserts of drugs ("**Circular 1**"). Circular 1 took effect on 1 June 2018 and repealed Circular No. 6/2016/TT-BYT, dated 8 March 2016 ("**Circular 6**"), on labeling of drugs, which was issued in accordance with the Law on Pharmacy No. 34/2005/QH11, dated 14 June 2005.

Under Circular 1, the package insert of drugs is an integral part of the drug label and shall be contained in secondary package of drugs or printed or affixed on the primary package of drugs in case where drugs have no secondary package. For the drugs and drug materials manufactured in Vietnam, the respective manufacturers and/or registrants shall be responsible for labeling. For drugs and drug materials to be imported, the drug importers and/or registrants in Vietnam shall have such responsibility.

Regarding drugs and drug materials to be imported, Circular 1 provides that if a drug or drug material imported into Vietnam, of which the original label's contents do not contain sufficient information as approved by the MOH, the importer must supplement the proper auxiliary labels in Vietnamese before marketing the same without removing the original label. However, in the following circumstances, the imported drugs are permitted for the clearance of custom procedures, and the package inserts in Vietnamese shall be supplemented or replaced later on:

(i) Imported drugs that already have Vietnamese product visas, with the Vietnamese package inserts in their commercial packages, which do not have updated contents as requested by the MOH, except for certain circumstances prescribed in the Points a, b, c and d, Clause 1 of Article 13 of Circular 1;

(ii) Imported drugs not yet having Vietnamese product visas and the Vietnamese package inserts in their commercial packages, except for certain circumstances prescribed in the Points a, b, c, d and đ, Clause 1 of Article 13 of Circular 1.

The supplementation or replacement of the Vietnamese proper auxiliary labels and/or package

inserts shall be conducted in accordance with the following principles: (i) the supplement of auxiliary label shall be performed at the importer's owned facility having GSP certificate; (ii) the supplementation and replacement of package inserts shall be performed at the secondary packaging division of a facility that have a GMP Certificate in accordance with the scope of Certificate of Eligibility for Pharmacy Business, and the supplementation and replacement of the package insert shall comply with GMP regulations, and be reported to the MOH within one month from the completion of such supplementation and replacement for the purpose of their State management and inspection; and (iii) the process of such supplementation and replacement must ensure the quality of drugs and drug materials.

Requirements for the contents of package inserts under Circular 1 have been simplified in comparison with the ones as provided in Circular 6. In particular, Circular 1 does not require separate drug information parts for persons in the medical art or for patients. In addition, Circular 1 specifies that the name of a drug may be the commercial one or the general international name, wherein the commercial name shall not, inter alia:

(i) be an advertisement for the drug;
(ii) mislead as to the ingredients, origins of the drug, and not be the name of a drug ingredient in case many ingredients are contained in the drug;
(iii) mislead as to the effects, applications, indications of the drug;
(iv) violate traditional values and customs of Vietnam;
(v) conflict with / infringe protected IPRs of other persons; and
(vi) be identical or similar with drug names that already have product visas and belong to other persons.

In addition, drugs having different ingredients shall not have the same names, and the names of drugs having the same active ingredients, drug materials, dosage form, administration route, concentrations, and manufacturer shall not be different from each other.

About Indochine Counsel

Established in October 2006, Indochine Counsel is one of the leading business law firms in Vietnam. The firm provides professional legal services for corporate clients making investments and doing business in Vietnam. The legal practitioners at Indochine Counsel are well qualified and possess substantial experience from both international law firms and domestic law firms. The firm boasts more than 45 legal professionals working at the main office in Ho Chi Minh City and a branch office in Hanoi.

Indochine Counsel's objective is to provide quality legal services and add value to clients through effective customized legal solutions that work specifically for the client. The firm represents local, regional and international clients in a broad range of matters including transactional work and cross-border transactions. The firm's clients are diverse, ranging from multinational corporations, foreign investors, banks and financial institutions, securities firms, funds and asset management companies, international organizations, law firms to private companies, SMEs and start-up firms in Vietnam.

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- Intellectual Property
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- Mining & Energy
- International Trade
- Dispute Resolution

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