KPMG

Technical Update

November 2023

1. Circular No. 16/2023/TT-BYT

On 15 August 2023, the Ministry of Health of Vietnam ("**MOH**") adopted Circular No. 16/2023/TT-BYT on marketing authorization ("**MA**") registration of drugs manufactured in Vietnam under a toll manufacturing arrangement ("**Toll-manufactured Drug**") and a technology transfer arrangement ("**Technology-transferred Drug**") ("**Circular 16**"), which came into effect on 1 October 2023 and superseded Circular No. 23/2013/TT-BYT dated 13 August 2013 of the MOH guiding toll manufacturing of drugs ("**Circular 23**"). Here are some notable changes under Circular 16:

a) Changes in regulations relating to the toll requestor and MA holder of Toll-manufactured Drug:

i. Circular 23 provides that the drug toll requestor is the party submitting the application dossier for issuing the MA of the toll-manufactured drug (and subsequently becoming the MA holder). Under Circular 16, the definition of the toll requestor has been changed for consistency with the prevailing Commercial Law: "a drug toll requestor is the party providing one, some, or all the materials, stages of the drug manufacturing process, technical documents proving the quality, safety, and efficiency of the drug to a drug toll processor under the toll manufacturing contract".

ii. For the MA holder, Circular 16 expands the circumstances under which an entity can become a MA holder. Accordingly, a drug toll requestor can itself be the MA holder or authorize another entity to be the MA holder of a Toll-manufactured Drug, provided that the drug toll requestor or the authorized entity must satisfy the conditions for being the MA holder of such Toll-manufactured Drug.

iii. If the MA holder is a Vietnamese-based entity, it must obtain the Certificate of Eligibility in doing Pharmaceutical Business ("**CEPB**") under one of the following business forms: manufacturing, wholesale, import or export of drugs or materials for manufacturing drugs. It means that a foreign invested enterprise ("**FIE**") with CEPB in drug import can technically act as the toll requestor under a drug toll manufacturing arrangement, though it does not have a manufacturing function. Note that, so far, a trading FIE (without having manufacturing function) may not be licensed to engage in toll manufacturing as the toll requestor due to the absence of law explicitly permitting the same. Therefore, with this regulation, if strictly and widely adopted by relevant authorities, it is expected that trading FIEs (though without having manufacturing function) would now be able to obtain the licence to engage in toll manufacturing as the toll requestors.

b) Roadmaps for implementation of the toll manufacturing under the toll manufacturing contract ("TMC") and transfer of manufacturing technology under the technology transfer contract ("TTC"):

Circular 16 requires the relevant parties to supplement the following new contents to the TMC/TTC:

i. the roadmap to (A) process all toll manufacturing stages of the Toll-manufactured Drug in Vietnam (for a TMC) or (B) transfer manufacturing technology of all manufacturing stages of drugs in Vietnam (for a TTC); and

ii. responsibilities of the relevant parties in respect of the Toll-manufactured Drug or Technology-transferred Drug. In particular, from the issuance date of the respective MA, the MA holder or the toll processor or technology transferee must annually submit a report on the implementation progress in accordance with the registered roadmap for toll manufacture or technology transfer to the MOH.

c) Online announcement of List of Toll-manufactured Drug and Technology-transferred Drug:

The Drug Administration of the MOH shall publish the List of Toll-manufactured Drug and Technology-transferred Drug granted with the MAs on its website and Health and Life Newspaper's website.

d) Shortening the drug registration time:

Circular 16 reduces the statutory timeline for the Drug Administration to process the MA application dossier to three (3) months (applicable for the MA application for Toll-manufactured Drug and Technology-transferred Drug), compared from six (6) months under the former Circular 23.

2. Decree 65/2023/ND-CP

On 23 August 2023, the Government issued Decree No. 65/2023/ND-CP on measures to enforce Law on Intellectual Property regarding industrial property, protection of industrial property rights, plant variety rights and State management of intellectual property ("**Decree 65**"), replacing Decree No. 103/2006/ND-CP dated 22 September 2006 and part of Decree No. 105/2006/ND-CP dated 22 September 2006, with some noteworthy points as follows:

a) Security control procedures of invention:

The security control procedures must be carried out for the inventions (in the field of engineering affecting security and defense were created in Vietnam and under the registration rights of individuals who are Vietnamese citizens and permanently reside in Vietnam or of organizations established under the laws of Vietnam) before the State management agency in charge of industrial property rights publishes such patent applications so that such inventions can satisfy the filing patent applications abroad.

b) Procedures for amendment, supplementation, separation, and withdrawal of an application for establishment of industrial property rights:

Procedures related to application for establishment of industrial property rights after submission of dossiers are stipulated clearly and specifically, and simplifies the administrative procedures at the State authorities, concurrently provides the applicants with flexibility in controlling such applications. Additionally, Decree 65 provides specific procedural guidelines for PCT forms, Hague forms, and Madrid forms.

c) Protective certificate:

A paper protective certificate shall only be issued upon request by the applicant in the application form. A request to amend the trademark on a protective certificate is only acceptable if the following conditions are met: (i) only minor details are excluded (without separate protection); and (ii) the distinguishability of the trademark are not altered. The procedures for issuance of derivative copy of or re-issuance of certificate on registration of contract for transfer of right to use industrial property object is similar to the procedures for issuing a protective certificate's derivative copy and re-issuing a protective certificate or a protective certificate's derivative copy.

d) Conditions on restriction of transfer of rights to trademarks:

Decree 65 sets out specific cases restricting the transfer of rights to trademarks specified in Clause 4, Article 139 of Law on Intellectual Property.

e) Secret inventions:

Decree 65 details procedures related to application dossiers for registration of secret inventions. Accordingly, a secret invention is an invention defined as a State secret under the Law on Protection of State Secrets 2018. An application for a secret invention must be submitted in paper form, and the timeline for appraisal of the dossier must not exceed 18 months. The State management agency in charge of industrial property rights shall coordinate with the Ministry of Public Security to determine whether information and documents in concern conform to regulations on protection of State secrets.

3. Official Letter No. 4040/TCHQ-GSQL

On 02 August 2023, the General Department of Customs issued the Official Letter No. 4040/TCHQ-GSQL on the conditions for inspection and supervision of the export processing enterprise ("**EPE**"), in particular:

i. If an EPE does not have enough space for a warehouse to store goods for its export processing activities within the export processing zone, industrial zone, economic zone, it can lease a space outside the industrial zone and economic zone, provided that the leased space has:

   (A) a hard fence surrounding such leased space to separate it from outside areas; and

   (B) surveillance cameras continuously operating at its entrance and exit doors and the customs authorities is entitled to access to the camera images, if necessary.

ii. The warehouse leased by EPEs is not required to have separate walls between the goods of such EPEs stored in such warehouse, if the warehouse satisfies the following conditions:

   (A) There is a hard fence surrounding such warehouse to separate it from outside areas;

   (B) Goods stored in the warehouse only consist of the goods of EPEs. If there are goods of non-EPEs in the warehouse, the warehouse must have a fence separating the goods of EPEs and goods of non-EPEs;

(C) Goods of EPEs stored in the warehouse must be separated, monitored 24 hours a day, and satisfy the requirements of the customs inspection and supervision; and

(D) The warehouse owner must have a mechanism to manage goods of each EPE when they are brought in, taken out and stored in the warehouse, and the warehouse owner must provide information (upon requested) and coordinate with the customs authorities to conduct inspections when there is sign of suspicious that the goods stored at the warehouse do not satisfy the conditions under laws.

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