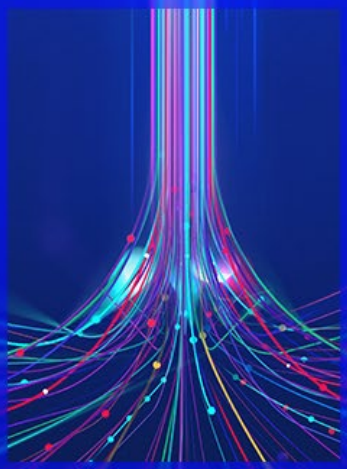
KPMG

# Technical Update

September 2022



## 1. Registration and management of foreign nongovernmental organizations in Vietnam

On 31 August 2022, the Government issued Decree No. 58/2022/ND-CP on registration and management of foreign nongovernmental organizations in Vietnam ("**Decree 58**"), replacing Decree 12/2012/ND-CP dated 1 March 2012 on the same subject matter. Decree 58 will take effect from 1 November 2022 with the following highlights:

- "**Foreign Non-Governmental Organization**" ("**Foreign NGO**") is defined as a non-profit organization, social fund, or a private fund, (i) established under foreign laws and carries out development assistance and humanitarian aid activities for not for profit or other purposes in Vietnam; and (ii) does not make financial contribution, call for sponsorships or raise funds from Vietnamese organizations and individuals.
- **Entitlement to operate in Vietnam**, Foreign NGO must satisfy the conditions such as having valid legal status, clear charter, principles, and goals. In addition, such Foreign NGO must also provide details about its planned programs, projects, and non-project activities to assist development and humanitarian aid in Vietnam in three years time and propose its representative in Vietnam.
- **Condition to obtain a representative office registration certificate**, Foreign NGO must not only satisfy the conditions such as valid legal status, clear charter, principles, and goals, but also have to commit to operate for a long term in Vietnam and list out the programs and projects to be implemented in Vietnam at least in five years time in one or several localities of which the size and nature require regular and on-site administration and supervision. In addition, Foreign NGO must propose its chief of the representative office in Vietnam.
- **Abolishing the provision on project office registration certificate**. Project office registration certificates granted according to Decree No. 12/2012/ND-CP will be modified, supplemented and re-granted in accordance with the provisions of Decree 58 until their expiry date; and will be converted into operation registration certificates or representative office registration certificates.
- **Database on Foreign NGO** (including a collection of information about Foreign NGOs and their operations) will be recorded on the National Public Service Portal and the Ministry of Foreign Affairs' public service portal, national database and databases of ministries, ministerial-level agencies, and government-attached agencies, People's Committees of provinces and centrally-run cities to assist the handling of administrative procedures related to registration and management of the operation of Foreign NGOs.
- **Specifically regulating on operation areas and fields of Foreign NGOs**; Suspension, termination of operation and revocation of registration certificates of Foreign NGOs; Rights and obligations of Foreign NGOs and responsibilities of the state management agencies and relevant agencies and organizations.

## 2. Electronic identification and authentication

In line with the trend of the development of e-commerce and the promotion of the industrial revolution 4.0, on 6 September 2022, the Government issued Decree No. 59/2022/ND-CP stipulating on the electronic identification and authentication ("**Decree 59**"). Decree 59 provides regulations on electronic identity, electronic identification and authentication; electronic authentication service;

rights and obligations of electronic authentication service users; responsibilities of relevant agencies, organizations and individuals. Decree 59 applies to Vietnamese agencies, organizations and individuals; foreign organizations and individuals residing and operating in the territory of Vietnam that are involved in electronic identification and authentication. Some notable points of Decree 59 are as follows:

- "Electronic identity" is defined as the information of an individual or an organization in the electronic identification and authentication system that enables the identification of a single person or organization in the electronic environment, while "Electronic identification" means the activities of registering, comparing, creating and attaching an electronic identity to an electronic identity owner.
- The electronic identity of the agency or organization established or registered for operation in Vietnam includes the electronic identification code; the organization's name comprises of the Vietnamese name, abbreviated name (if any) and a foreign language name (if any); date, month, year of establishment; head office address; and personal identification number or identification number of a foreigner; full name of the legal representative or head of the organization.
- Contains regulations on electronic identity accounts ("**EIA**"), procedures for registration of EIA for Vietnamese citizens, foreigners and organizations, statutory timeline for providing EIA. Accordingly, EIA of an agency or organization is a level-2 account and is registered by the legal representative, the head of the organization through the VNeID application.
- EIA of an agency or organization is valid for proving the electronic identity of such agency or organization and providing the information in its documents for comparison by competent authorities. When an agency or organization uses an EIA in electronic activities and transactions, it will have the same value as the presentation of papers and documents for proving the information has been integrated into the electronic identification account.

## 3. Regulations on drugs subject to bioequivalence testing and requirements for report of bioequivalence study data when registering drugs in Vietnam

On 05 September 2022, The Ministry of Health issued Circular No. 07/2022/TT-BYT stipulating on drugs that must be tested for bioequivalence and requirements for the application for reporting bioequivalence study data when registering drugs circulation in Vietnam ("Circular 07"). Circular 07 will take effect from 1 November 2022, replacing Circular No. 08/2010/TT-BYT dated 26 April 2010 guiding report of bioavailability/bioequivalence study data when registering drugs, with some notable points as below:

- Generic drugs containing pharmaceutical substance or in dosage form will require a bioequivalence study data report, while generic products with bioequivalence properties with comparator products are exempt from this requirement.
- Sets out the selection criteria for pharmaceutical substance contained in generic drugs that requires s report bioequivalence study data report when registering for circulation in Vietnam and criteria for selection of comparator products used in bioequivalence tests serving for circulation registration.
- Providing regulations for bioequivalence studies in bioequivalence study data reporting records and specific guidelines for application on reporting bioequivalence study data of generic drugs.

## 4. Registration for circulation of drugs and medicinal ingredients

The Ministry of Health also recently issued Circular No. 08/2022/TT-BYT on circulation registration of drugs and medicinal ingredients ("**Circular 08**"). Circular 08 will take effect from 20 October 2022 and includes regulations to streamline a series of administrative procedures in the field of circulation registration for drugs and medicinal ingredients as compared to the former regulations in Circular No. 32/2018/TT-BYT. Some notable points in Circular 08 are as follows:

- Drugs of the same manufacturer with the same active ingredients or herbal ingredients; dosage forms, route of administration; content or concentration of active ingredient per unit dose (except for drugs that are processed and manufactured for export purposes only) can be registered in 1 circulation registration certificate under the trade name and in 1 circulation registration certificate under the international nonproprietary name.
- Stipulating on cases where drugs are classified as proprietary drugs and reference biological products as well as criteria for classifying drugs with demonstrated bioequivalence.
- Applications for small modifications are only required notification and are not subject to appraisal and approval by competent authorities. In addition, the number of documents to be submitted in the application for issuance, renewal of circulation registration certificate is also reduced.

- Abolishing the requirements on the form of authorization letter, instead provides the mandatory content for an authorization letter, the authorizing persons signatures will no longer require the authentication, as the Ministry of Health determines that the authorization letter is an internal business document.
- Registrants are only allowed to amend and supplement no more than 03 times for dossiers.

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