**PROCEDURES ON APPLICATION FOR IMPORTING MEDICAL EQUIPMENT LICENSE**

Due to the increasing demand for medical examination and treatment, the import of medical equipment from abroad also becomes popular. However, the import of medical equipment needs to go through a lot of processes and procedures from state agencies due to the specific characteristics of these goods. Among them, the procedure for applying for an import license is one of the issues that importers are very concerned about. Here are some of our consulting information related to the above issue.

1. **Cases where medical equipment import licenses are required**

According to the provisions of Article 3 of Circular 30/2015/TT-BYT of the Ministry of Health, the issuance of medical equipment import license only applies to the imported medical equipment included in the List specified in Annex 1 issued with this Circular.

The medical equipment not included in the List specified in Appendix 1 issued with Circular 30/2015/TT-BYT shall be imported without the import license but must still ensure the dossier to trace their origin and quality management of medical equipment as prescribed by law.

1. **Procedures for applying for importing medical equipment license**

***Step 1: Submit the application to the Ministry of Health***

Application includes:

* The written request for the new issue of medical equipment import license of the organizations or individuals is under Form No.01 specified in Appendix 2 issued with Circular 30/2015/TT-BYT;
* Valid Certificate of free sale of types of imported medical equipment at the time of submission of the dossier;
* The valid ISO 13485 or ISO 9001 quality systems certification of the manufacturer at the time of dossier submission;
* The valid Power of Attorney from medical equipment owners to organizations or individuals importing the medical equipment under the Form specified in Appendix III issued with Circular 30/2015/TT-BYT at the time of dossier submission;
* The technical material describing the types of medical equipment in the Vietnamese language under Form No. IV issued with this Circular 30/2015/TT-BYT;
* Catalog describing the functions and technical parameters of types of imported medical equipment;
* Clinical evaluation documents and user manuals of the owner or manufacturer for various types of interventional devices and materials in cardiology, cranial nerves;
* Report on the result of the import of medical equipment by the time of dossier submission for the new issue of medical equipment import license in the case where the import license has expired without renewal.

***Step 2: The Ministry of Health review the completeness and validity of the application file for a new import license***

Within five (05) working days from the date indicated in the Application receipt, the Ministry of Health shall review the completeness and validity of the dossier for new issue of import license.

**In case the dossier is complete and valid**, the Ministry of Health shall hold a meeting of its consultation Council for the issue of medical equipment import license for review and opinions to the dossier for the new issue of import license within ten (10) working days from the date indicated in the Application receipt.

* Where the consultation Council has no requirement for amendment or addition of import dossier and agrees to issue the import license, the Ministry of Health shall issue the new import license within 10 working days from the date of minutes of the meeting of consultation Council. The date of the minutes is considered the date of the meeting of the Council;

Based on such minutes, the Minister of Health shall consider and decide the issue of medical equipment import license and reply in writing in case of disapproval for the issue.

* Where the consultation Council requires amendment or addition of dossier:
	+ Within five (05) working days from the date of minutes of the consultation Council meeting, the Ministry of Health must give written notice to the importing unit for amendment or addition of importing dossier. The written announcement should specify which documents; contents need additional or amended. The notice of dossier completion is doing only one time except for the case of contents which the Ministry of Health has given the notice of completion but the unit requesting import has failed to complete them or improperly complete as required by the Ministry of Health;

* + When receiving the written requirement for amendment or addition of import dossier, the importing unit must amend or add it in accordance with the contents specified in the written requirement and send such dossier to the Ministry of Health;
	+ Where the importing unit has amended or added the import dossier but improperly with the requirement, the Ministry of Health shall notify the importing unit for further completion of importing dossier;
	+ In case of having the requirement for amendment or addition on import dossier but after sixty (60) days after the Ministry of Health gives written notice of amendment or addition of import dossier but the importing unit fails to comply with such requirement, the Ministry of Health shall refuse to further review such dossier.

**In case the dossier is incomplete or invalid:** Within ten (10) working days from the date recorded on the Application receipt, the Ministry of Health gives written notice to the importing unit for amendment or addition of import dossier. The written notice must specify which document or content needs amend. The announcement of dossier completion is doing only one time except for the case of contents which the Ministry of Health has given the notice of completion but the unit requesting import has failed to complete them or improperly complete as required by the Ministry of Health.

**Note:** After sixty (60) days after the Ministry of Health gives written notice of amendment or addition of import dossier but the importing unit fails to comply with such requirement, the Ministry of Health shall refuse to further review the import dossier.

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