Procedure for issuing import and export declarations for medicines and medical devices has been approved

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In Brief

On June 5, 2024, the Parliament of Mongolia adopted the Revised Law on Medicines and Medical Devices ("**LMMD**"). The LMMD took effect on October 1, 2024, introducing significant changes to the pharmaceutical and medical sectors.

Following the LMMD's adoption, various secondary regulations are anticipated to be revised. In this context, the Procedure for issuing import and export declarations for medicines and medical devices was revised on October 18, 2024 (the "**Procedure**").

The Procedure aims to regulate the process of requesting and issuing import and export declarations for medicines and medical devices. It applies to the import and export of medicines and medical devices, with exceptions for narcotic and psychotropic drugs, their precursors, health supplements, disinfectants, and medicines and medical devices for personal use.

Main provisions under the Procedure

The Procedure contains the following regulations:

- General regulations for import and export declarations;
- Necessary documents for obtaining import and export declarations;
- Procedures for requesting and issuing import and export declarations;
- Grounds for invalidation or modification of import and export declarations;
- Rights and obligations of issuers and requesters of import and export declarations;
- Standard forms for declarations.

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Main considerations

We summarize below the main considerations under the Procedure.

1.	**License**	A requestor of declaration must have a license specified under the LMMD.
2.	**Access Code**	Before submitting an application, a requestor must obtain an access code for the Licemed electronic database from the Medicine and Medical devices Regulatory Authority.
3.	**Submission requirement**	Declarations must be requested on each occasion of importation or exportation and multiple declarations cannot be requested with a single application.
4.	**Online tracking**	The status of application processing can be viewed online.
5.	**Prohibitions**	It is prohibited to transfer, sell, gift, pledge, alter, or counterfeit the declaration.
6.	**Registration**	In order to be imported, medicines, active pharmaceutical ingredients, medical equipment, medical supplies, and laboratory diagnostic tools must be registered in Mongolia or listed in the medical device registry. This requirement does not apply in certain exceptional cases.
7.	**Standard requirements**	For importing medicines and medical devices, it is necessary to submit documents on standard requirements. For example, for medicines, a good manufacturing practice certificate from the manufacturer is required, and for medical devices, a certificate of implementation of the 'Quality Management System for Medical Devices' (ISO:13485) from the manufacturer is required. Additionally, a CE certificate is required if necessary.
8.	**Processing time**	Applications are generally reviewed and decided upon within 5 working days after the submission.
9.	**Modifications**	The declaration can be amended If it is necessary to change the validity period of the declaration, the name, type, port, or quantity of the medicines and medical devices. In this case, an official request must be submitted along with the relevant supporting documents.
10.	**Violations**	If a requestor has violated the Procedure, such as by providing false documents or information on more than two occasions, the declaration will be invalidated. The issue of suspending or revoking the license will then be decided by the Medicine and Medical Devices Regulatory Authority.
11.	**Reporting**	A requestor is required to submit a report on the imported or exported medicines and medical devices based on the declaration to Medicine and Medical Devices Regulatory Authority in electronic form by January 15th of the following year.

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If you are interested in legal advice on Law on Medicines and Medical Devices, and secondary regulations, please contact us.

If you wish to view the full text of the Procedure, please click here.

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