Registration Procedures for medicines, medical devices and health supplements and key provisions

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In Brief

In connection with the revised Law on Medicines and Medical Devices ("**LMMD**") which came into effect on October 1, 2024, the following procedures were adopted on May 26, 2025, by the Order No. A/206 of the Minister of Health:

- Procedure for Registration of Medicines and Active Pharmaceutical Ingredients;
- Procedure for Registration of Medical Devices; and
- Procedure for Registration of Health Supplements.

These new procedures replace the previous 2019 Procedure for Registration of Medicines, Raw Materials, and Biologically Active Products ("**Previous Procedure"**), which is now repealed. Given the critical role these procedures play in the registration of medicines, medical devices, and health supplements, this newsletter summarizes the key changes and core regulatory provisions introduced in each of the three new procedures.

Procedure for Registration of Medicines and Active Pharmaceutical Ingredients

The registration of medicines is now governed by the newly adopted Procedure for Registration of Medicines and Active Pharmaceutical Ingredients, which introduces the following changes.

1. **Registration Process and Timelines** – There have been minor changes to the overall registration process. Specifically, the revised regulation provides clearer guidance on the use of the Ebusiness and Licemed systems during the registration process, including the submission of relevant documents and information.
2. **Licemed Database Requirements** – The new procedure slightly expands the types of information required for the Licemed system. For instance, a summary of product characteristics is now required to be entered into the system. This includes various details such as the medicine's name, dosage form, composition, strength, clinical information, shelf life, list of excipients, and precautions for use and disposal, among others.
3. **Changes to the Registered Information** – Contrary to the Previous Procedure, the new procedure provides detailed guidance on how to handle changes to registered products. According to the new procedure, changes are categorized as either major or minor, depending on the extent of the modification.

Procedure for Registration of Medicines and Active Pharmaceutical Ingredients (Cont'd)

The table below outlines the types of changes to registration and the corresponding actions.

№	Types	Changes	Appropriate Actions
1.	**Major Change**	Changes in the active pharmaceutical ingredient, the quantity of the active ingredient, general characteristics, dosage form, route of administration, and indications and dosage.	Re-registration is required.
		Changes in the stability of the active pharmaceutical ingredient and the final product, manufacturing site, address, manufacturing process, summary of product characteristics, and instructions for use and other items.	These changes are subject to review and decision by the Medicines Council.
2.	**Minor change**	Changes such as the registration holder organization, and the design, size, or shape of the primary and secondary packaging.	These changes must be registered with the MMDRA.

4. **De-registration** – While the Previous Procedure did not provide detailed guidance on the de-registration process, the newly adopted procedure introduces the following provisions:
   - If the registrant decides not to renew the registration or if the manufacturer requests de-registration, the registrant must submit a formal notification to the Medicine and Medical Regulatory Authority ("**MMDRA**") stating the reason for de-registration.
   - The registrant must confirm that there is no remaining stock of the product on the market.
   - The registrant must notify consumers, healthcare professionals, and healthcare institutions in advance about the de-registration of the product.

Procedure for Registration of Medical Devices

Under the LMMD, medical devices in Mongolia are classified into three categories: laboratory diagnostic devices, medical equipment, and medical supplies. Medical devices that fall under medium and high-risk categories must be registered. The registration process varies depending on the type of device. The newly approved Procedure for Registration of Medical Devices provides detailed procedures for registering laboratory diagnostic devices and including medical equipment and supplies in the official medical device list. Below is a summary of the key regulatory provisions:

1. **Laboratory Diagnostic Devices** – Diagnostic devices are registered for a period of five years and must be issued a certificate. The manufacturer, through a supply organization or an official representative, may register, renew, amend, or request the de-registration of a laboratory diagnostic device. The new procedure specifies the required documentation for each case, including initial registration, amendments, renewal, and de-registration.

2. **Medical Devices List** – Medical equipment and supplies are registered by being listed in the official medical device list. Once listed, these devices can be legally imported and exported.

Procedure for Registration of Medical Devices (Cont'd)

In order to include medical equipment and medical supplies in the list of medical devices, the registrant must submit the following documents to the MMDRA. These include:

- Official request from the registrant organization
- Application for inclusion in the list
- Manufacturer's profile
- Copy of the ISO 13485 quality management system certificate (certified by the manufacturer)
- Marketing authorization or free sales certificate of the product
- Detailed product description and technical specifications
- Images of the external appearance and full set of components
- Labeling and marking information
- Instructions for use, along with Mongolian translation
- Document verifying that the software functions as intended (applicable only to devices with software)
- Verification report demonstrating compliance with technical specifications
- Official letter from the manufacturer identifying the supplier responsible for fulfilling the obligations under Article 40.8 of the Law on Medicines and Medical Devices (applicable only to medical equipment)

Procedure for Registration of Health Supplements

The newly adopted Procedure for Registration of Health Supplements, provides detailed provisions related to the registration of health supplements.

1. Required Documents for Registration

According to this procedure, various documents must be submitted when applying for registration of a health supplement. These include a copy of the registrant's state registration certificate, confirmation of the quality and safety of the product during use, manufacturer's certificate of Good Manufacturing Practice (GMP) or implementation of a quality management system or food safety system (ISO 9001, ISO 22000, ISO 17025:2018, HACCP) among other documents.

2. Cancellation of Registration

The updated procedure also introduces specific provisions for the cancellation of health supplement registrations. A health supplement's registration will be invalidated under the following circumstances:

1. Surveillance, inspection, or testing results determine that the product does not meet quality or safety requirements
2. It is determined that the registration documents were falsified
3. It is determined that illegal advertising was conducted or misleading information was disseminated to consumers
4. A formal request for cancellation is submitted by the registrant or the manufacturer

Contact us!

If you need legal advice regarding medicines, medical devices, active pharmaceutical ingredients, or health supplements, please don't hesitate to contact us. If you would like to read the full versions of the procedures, please use the following links.

- Procedure for Registration of Medicines and Active Pharmaceutical Ingredients;
- Procedure for Registration of Medical Devices; and
- Procedure for Registration of Health Supplements.

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