



Overview and Outlook on the Recently Implemented Medical Device Liability Insurance System

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1. Background

Until recently, through various laws, the Korean government has been implementing consumer protection by mandating that companies in certain specific industries purchase insurance, such as the *Framework Act on the Management of Disasters and Safety*, the *Industrial Convergence Promotion Act*, the *Guarantee of Automobile Compensation Act*, the *Special Act on the Safety Control of Publicly Used Establishments*, the *Urban Gas Business Act*, and the *Elevator Facilities Safety Management Act*). However, for the medical device industry, there was no such legal framework. Therefore, if a patient suffered injury or illness related to the use of a medical device, he/she had no other option, but to resort to individual lawsuits under the *Product Liability Act* or *Civil Act* to claim compensation for damage arising from medical device(s) that he/she had used.

This has now changed. A provision was added to the Medical Devices Act (specifically, Article 43-6), newly requiring medical device manufacturers and importers to purchase liability insurance, based on which patients using medical devices may benefit from insurance payments. This amendment became effective on July 21, 2022.

[Article 43-6 of the Medical Devices Act \(Insurance, Etc.\)](#)

- ① Medical device manufacturers and importers, as prescribed by the Presidential Decree, shall purchase insurance or join a mutual aid to compensate for damages incurred by patients due to material side effects or death which occurred while using a medical device.
- ② Under paragraph 1 above, the types of insurance or mutual aid, medical device manufacturers and importers who are mandated to purchase insurance, insured amounts and other necessary matters shall be prescribed by the Presidential Decree.

2. Key Changes to the Medical Devices Act & the Enforcement Decree

1. **Eligibility for insurance coverage:** Under the Presidential Decree of the Medical Devices Act (“**Enforcement Decree**”), manufacturers and importers of “implantable medical devices” (i.e., those medical devices that pose a high level of risk to the human body and/or are known to have caused numerous cases of adverse events related to its use) are obligated to purchase medical liability insurance.

[Article 12-5 of the Enforcement Decree of the Medical Devices Act \(Medical Device Manufacturers and Importers Who Are Mandated to Purchase Insurance or Mutual Aid and Types, Etc. Insurance or Mutual Aid\)](#)

① Manufacturers and importers, as prescribed by the Presidential Decree under Article 43-6(1) of the Medical Devices Act, and those who are mandated to purchase insurance under paragraph 2 of the same Act means manufacturers and importers of medical devices, which are inserted into and intended to remain in a human body for no less than thirty (30) consecutive days (hereinafter, the “**implantable medical devices**”).

2. **The insured and insurance amount, among others:** Insurance is paid to patients in the event of death (minimum KRW 150 million), casualty (minimum 30 million), sequelae (minimum KRW 150 million) after the enforcement date of the medical device insurance scheme (July 21, 2022).

[Article 12-6 of the Enforcement Decree of the Medical Device Act \(Insured Amount Etc. for Medical Device Liability Insurance, Etc.\)](#)

① The insured amount for medical device liability insurance, etc., shall not be less than the following amount:

1. **In the event of death:** KRW 150 million per person;
2. **In the event of injury:** KRW 30 million per person; and
3. **In the event of bodily disability caused by an injury where, after the completion of treatment of such injury, the symptoms caused by such injury become fixed, allowing no further expectations for progress** (hereinafter, “**sequelae**”): KRW 150 million per person.

3. **Time of insurance subscription:** While similar laws provide that the insurance should be purchased prior to the initial release/launch of the product, the Medical Devices Act provides that manufacturers and importers of implantable medical devices should purchase liability insurance prior to the sale of such a medical device.

4. **If an overseas manufacturer or distributor has already purchased insurance policy in another country outside of Korea:** To the extent that such foreign insurance policy satisfies the conditions (e.g., amount of compensation) prescribed by the Medical Devices Act and covers damages incurred by patients in Korea, the medical device manufacturer/importer is not required to purchase a separate insurance in Korea.

5. **Administrative sanctions:** Medical device manufacturers and importers, who fail to purchase medical device liability insurance, despite being required to do so under the medical device insurance legal rules, will be subject to: (i) a

warning, a type of administrative sanction for the first violation; (ii) temporary suspension of sale of the relevant product for one month for the second violation; (iii) temporary suspension of sale of the relevant product for three months for the third violation; and (iv) prohibition of the sale of the relevant product (for the fourth or more violation).

6. Grace period: Medical device manufacturers/importers are granted a grace period of six months from the enforcement date of the current Enforcement Decree of the Medical Device Act (i.e., 6 months from July 21, 2022) for meeting the legal obligation to purchase medical device liability insurance.

Enforcement Decree of the Medical Device Act, Addenda Article 2 (Applicability of Those Subject to Medical Device Liability Insurance, Etc., and Special Exceptions Regarding Time of Purchase)

① The amendments to Article 12-5 and Article 12-6 of the Enforcement Decree shall also apply to implantable medical device manufacturers and importers, who obtained a medical device manufacturing permit or manufacturing certification, or importing permit or importing certification (however, those manufacturers/importers, who have obtained a manufacturing permit/manufacturing certification or importing permit/importing certification solely for the purpose of exporting are excluded).

② Notwithstanding the amended Article 12-6(2) of the Enforcement Decree, implantable medical device manufacturers and importers under paragraph 1 above shall subscribe to a medical device liability insurance, etc., within six (6) months from the date of enforcement of this Enforcement Decree.

3. Outlook & Potential Implications

1. **Potential for the scope of obligation to expand:** Currently, certain insurance companies are selling medical device liability insurance products that have been reviewed by Korean financial supervisory authorities. Once the current medical device insurance scheme is well on track, the obligation to purchase medical device liability insurance will likely be expanded to manufacturers/importers of “non-implantable medical devices” or voluntary insurance subscription may be recommended for “all medical devices”.

2. **Need to closely monitor regulatory developments and consider taking appropriate measures:** As of 2020, the estimate market size for “implantable medical devices” is approximately KRW 1.07 trillion. The annual premium payable by manufacturers and importers of “implantable medical devices” under the scheduled medical device liability insurance scheme is expected to reach billions of Korean Won. Going forward, it is expected to increase.

- Once the grace period for purchasing medical device liability insurance elapses (6 months from July 21, 2022, as per the Enforcement Decree), the Korean government will likely conduct a survey/assessment on the purchase of medical device liability insurance. Also, the Korean government may impose administrative sanctions to non-compliant manufacturers and importers, who failed to purchase medical device liability insurance in violation of the law.
- As such, it would be prudent for medical device manufacturers and importers to closely monitor the related developments and take appropriate measures, such as purchasing medical device liability insurance, among

others.

[\[Korean version\]](#) 최근 시행된 '의료기기 책임보험제도'의 개요와 전망

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