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## MFDS Sets Standards for Safe Use of Zolpidem and Propofol

Check on the past medical history of patients to make sure that

- “zolpidem” is not used on patients under 18 or were prescribed with “zolpidem” in the last 4 weeks; and that
- “propofol” is not used more than once every month on a patient

□ The Ministry of Food and Drug Safety (MFDS, Minister Lee Eui-Kyung) established and published the standards for safe use to promote the proper use and prescription of two narcotic medicines, “zolpidem” and “propofol.”

※ (zolpidem) psychotropic drug used for the treatment of insomnia in adults,  
(propofol) psychotropic drug used to induce and maintain the general anesthetic state

○ The standards was established through the decision of the second meeting of the “Narcotics safety management review committee<sup>※</sup>” held on Aug. 31 to ensure the safe use and prevent the misuse and abuse of “zolpidem” and “propofol.”

※ The committee is comprised of approximately 20 experts commissioned by the Minister of Food and Drug Safety according to Article 5-3 of the “Narcotics Control Act,” to discuss on the standard procedures for the prevention of narcotics misuse and abuse, and the standards for the safe use of narcotics, among other matters.

- In fact, the newly provided standards were reviewed and improved through the works of expert committees<sup>1)</sup>, based on the contents of MFDS’s research project<sup>2)</sup> organized by the Korean Medical Association.

1) (for zolpidem) comprised of Korean Medical Association, Korean Pharmaceutical Association, Korean Neurological Association, among others

(for propofol) comprised of Korean Medical Association, Korean Society of

Anesthesiologists, Korean Association of Plastic Surgeons, among others

- 2) The first part of the project on three drug categories (appetite suppressants, zolpidem, propofol) out of the three-year-plan (scheduled to be held from 2019 to 2021) was completed in 2019.

□ Some of the highlights of the publication on the standards are as follows:

- The use of “zolpidem” must be approached with caution as it can lead to drug abuse and dependence. The prescribed dosage of zolpidem should not exceed 10 mg per day.

- In addition, zolpidem’s drug use period should not exceed 4 weeks, and zolpidem should not be used on patients under 18.

- Medical professionals must properly adjust propofol dose based on the patient’s weight, always bearing in mind that propofol has a high risk of misuse and abuse. Propofol should not be administered independently without reasons related to surgery, surgical procedures, or medical examinations.

- Also, it is advised that the number of propofol injection for simple surgical procedures does not exceed once every month and that medical professionals check on the patient’s propofol usage history before prescribing.

□ The MFDS is applying “Advance notice” system and “voluntary reporting” systems along with the “Standards for safe use” for two narcotic medicines(“zolpidem” and “propofol”).

- “Advance notice” system allows the analysis of data reported via Narcotics Information Management System and sends written notifications to doctors suspected of over- or mis-prescribing narcotic medicines deviating from the standards for safe use.

- “Voluntary reporting system” allows doctors to make reports in advance when s/he has inevitably prescribed or administered narcotic medicines in the amount or frequency that deviate from the standard for safe use.

- The MFDS will stay committed to create an environment where people can safely access narcotic medicines free of misuse and abuse and to protect public health from the harm caused by narcotic drug abuse.