

EDITOR'S NOTE: Below is an English translation of a YNA story headlined 탈모 치료제 프로페시아, 우울증·자살생각 '경고' that can be accessed here.

Yonhap News Agency July 4, 2017

Warning Against Depression and Suicidal Thoughts Induced by Hair-Loss Medication Propecia The Ministry of Food and Drug Safety changes warning labels for 142 items By Jandi Kim, Seoul

Warning labels will be added to finasteride (commonly known as Propecia), which is used to treat male hair loss and enlarged prostate, noting that the prescription medication may cause side effects including depression and suicidal thoughts, among other things.

The Pharmaceutical Safety Assessment Division of the Ministry of Food and Drug Safety (MFDS) announced the warning July 4 based on a safety report submitted by MSD Korea, which originally developed the drug.

142 items and 98 pharmaceutical companies, including MSD Korea's Propecia, are subject to such warning. Except for Propecia, all items are generic drugs containing the same ingredients.

Propecia is the world's first male-pattern hair-loss medication approved by the US Food and Drug Administration. It was originally developed as a prostate-enlargement drug but became a hair-loss therapy in 1997, after clinical evidence backed its hair-growth efficacy.

Propecia was released in the Korean market in 2000. When its patent expired in 2008, several generic drugs were also released in the market. However, Propecia has ranked No. 1 in the hair-loss drug market the whole time. Sales of the drug reportedly topped 35 billion Korean won in 2016.

There are presently more than 60 generic hair-loss drugs and 70 generic prostate-enlargement drugs on the market that have the same ingredients as Propecia.

Korean doctors tend to prescribe Monad (JW Shinyak) and Finated (Hanmi Pharm Co.) most among the generic versions of finasteride. Of those two, Monad has enjoyed the highest sales revenue last year, bringing in 6.6 billion Korean won.

A source from the MFDS said, "MSD Korea reported the side effects which had occurred overseas in Korea." and added that "accordingly, the Ministry is considering adding a warning label depending on the results of the safety review, and asked [the industry] for feedback."

The MFDS is scheduled to receive feedback on the approval revision by July 14, and complete the approval revision based on due process.