February 21, 2014

Notification of approval of additional ‘indication’ and ‘dosage and administration’ of the estradiol transdermal patch Estrana® Tape 0.72 mg

Hisamitsu Pharmaceutical Co., Inc., (Head Office: Tosu city, Saga Prefecture, Japan; President and CEO: Hirotaka Nakatomi; hereinafter referred to as “Hisamitsu”) announced that today Hisamitsu obtained approval for the additional ‘indication’ and ‘dosage and administration’ of the estradiol transdermal patch Estrana® Tape 0.72 mg (Active pharmaceutical ingredient : estradiol, hereinafter referred to as “the product”) for treatment of hypoestrogenism due to hypogonadism or other reasons.

The product is a patch formulation compounded with estradiol, which is a type of female hormone, as an active pharmaceutical ingredient. It was launched in February 2000 with the indication of vasomotor nerve symptoms associated with menopausal disorders and ovarian deficiency symptoms, and the additional indication of postmenopausal osteoporosis was approved in April 2002.

In regards to the addition of the ‘indication’ and ‘dosage and administration’ of this drug, an evaluation was conducted by the Evaluation Committee on Unapproved or Off-Labeled Drugs with High Medical Needs on March 23, 2012. As a result, the drug was evaluated to have high medical needs and development was requested by the Ministry of Health, Labor and Welfare. Following this, the product was allowed for public knowledge-based application by the First Committee on Drugs, Pharmaceutical Affairs, and Food Sanitation Council on August 2, 2013, and Hisamitsu submitted the application for partial changes to the approved items (public knowledge-based application) on August 30, 2013.

Hisamitsu expects that the product will contribute to an improvement in the QOL of more patients and will be actively involved in the resolution of unapproved and off-labeled drugs with high medical needs.

Reference

(1) Public knowledge-based application

This is a system for the approval of pharmaceuticals (addition of indication, etc.) where the application for approval can be submitted without newly conducting the whole or a part of the clinical studies if the efficacy and safety of the pharmaceutical is regarded as publically known from the medical and pharmacological perspective.

(2) Evaluation Committee on Unapproved or Off-Labeled Drugs with High Medical Needs

This is a committee established by the Ministry of Health, Labor and Welfare to evaluate the medical needs for pharmaceuticals and indications that are approved in the United States or Europe but not in Japan (hereinafter referred to as “unapproved and off-labeled drugs”), as well to confirm the appropriateness of the public knowledge-based application and the feasibility of additional studies for the approval application. The purpose of this committee is to contribute to the promotion of development of unapproved and off-labeled drugs by pharmaceutical companies.