SINECCH capsule PMS(Post Marketing Surveillance) Report

SinEcch was determined to be suitable for safety and efficacy as a prescription drug by KFDA through PMS.

SinEcch got a conditional approval when it was initially licensed in Korea.
It should go through medicine reexamination proceeding after PMS for 4 years in order to achieve a permanent approval.
PMS had been carried out at 19 hospitals on 650 people for 4 years since its permit in 2008. During PMS, any single adverse side effects had not been reported. It was evaluated as a very effective drug for bruising and swelling.

SINECCH PMS Summary

PMS Purpose

Safety validation for SinEcch as a surgery bruising and swelling medicine through post-marketing survey.

Research Institutions

19 institutions including university hospitals, general hospitals and specialist clinics around the plastic surgeons.

Survey Target

650 surgery patients in university hospitals, general hospitals and plastic surgery clinics.

Survey Period

8 Oct 2008 (the day of conditional approval in Korea) until 7 Dec 2012 (4 years) / Six Primary Research Conducted.

PMS Report Summary

- No adverse effects through PMS in safety section.

- The degree of relevance of demographic and factor specific characteristics (gender, inpatient status and whether to use drugs in combination) to the amount of bruising and swelling was analyzed in efficacy section.
  It got the general comments of “improvement” from all patients taking SinEcch.
  (According to PMS survey self-evaluation data, SinEcch was effective more than 93% on bruising and swelling)

* The evaluation methods of other safety and effectiveness and result reports are described in detail in an attached file named by PMS report.

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