2007 Erratum

2007 American College of Rheumatology Annual Scientific Meeting - Abstract 344 - Safety Outcomes from a Large Japanese Post-Marketing Surveillance for Etanercept

Author(s):
Takao Koike1, Masayoshi Harigai[1], Shigeko Inokuma[1], Kazuhiko Inoue[1],Naoki Ishiguro[1], Jyunnosuke Ryu[1], Tsutomu Takeuchi[1], Yoshiya Tanaka[1],Hisashi Yamanaka[1], Michio Suzukawa[2], Koichi Fujii[2], Bruce Freundlich[3.1]Japan College of Rheumatology Etanercept Post-Marketing Surveillance Committee, Tokyo, Japan;[2] Wyeth KK, Medical Affairs, Tokyo, Japan;[3]Wyeth Research, Global Medical Affairs, Collegeville, PA

Disclosures:
T. Koike, None; M. Harigai, pharmacovigilance of biologics, [2];S.Inokuma, None; K. Inoue, None; N. Ishiguro, None; J. Ryu, None; T.Takeuchi, None; Y. Tanaka, None; H. Yamanaka, None; M. Suzukawa, None; K. Fujii, None; B. Freundlich, None.

The following information should have be appeared on the above abstract:
The Japan College of Rheumatology Etanercept Post-Marketing Surveillance Committee was created in response to a request for assistance to the JCR from the Ministry of Health, Labor and Welfare (MHLW) of Japan. The role of the Committee was to provide independent advice to Wyeth K.K. on the conducting of the Post-Marketing Surveillance Program mandated by the MHLW. Participation on this Committee was not compensated. The PMS Program was sponsored by Wyeth Research and the clinical fees were shared by Wyeth Research Japan and Takeda Pharmaceutical Company limited.

Japan has a unique regulation concerning post marketing surveillance (GPSP) and a re-examination. This PMS Program was conducted by Wyeth as condition of the product approval under the Pharmaceutical Affairs Law and the regulation promulgated thereunder, and the MHLW determined the parameters of the PMS Program e.g., number of patients, qualifications of investigators, duration etc.

****