

全例調査をどう考えるか**

—産より(2)：アリムタ適正使用の観点からの全例調査の役割—

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**Role of Alimta Drug Registry Type Surveillance Study
from the Viewpoint of Proper Drug Use**

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Summary

Alimta (Pemetrexed) is an anti-cancer drug for treatment of malignant pleural mesothelioma. It was submitted on June 2006 with data on 25 Japanese patients and approved in January 2007. Due to the limited number of Japanese patients and the issue of drug-induced interstitial lung disease (ILD) by other agents, a drug registry type surveillance study was required as a condition of approval. The main objectives of this study were to investigate serious adverse drug reactions, especially ILD, and to gather safety information in a "real world" setting after launch.

This study was started just after approval/launch and patient registration was completed in May 2008. The target number of patients was 300, and finally about 950 patients were registered. We have been implementing the study with three risk minimization activities, i.e., drug access control, training for relevant persons including HCPs, and quick/timely safety information disclosure.

We confirmed that Alimta was used in the recommended manner in the selected hospitals based on our criteria. It is important to note that physicians were asked to deliver safety information to the sponsor as quickly as possible, so that their workload was consequently increased. Therefore, it is important to consider the incremental workload in order to conduct such a study smoothly.

The study has several methodological aspects from the viewpoint of the ICH E2E guideline "Pharmacovigilance planning", and the status of this type of study is currently unclear.

Considering that Japanese patients are increasingly being enrolled in global studies, further discussion is necessary to develop a more efficient, specifically designed risk management system.

Key words

Alimta, Malignant Pleural mesothelioma, Approval condition, Proper use, Drug registry type surveillance study, Access control, Drug-induced interstitial lung disease, Pharmacovigilance planning