

承認から臨床への安全な導入—現場での対応—\*\*\*

—スニチニブ：産より—

開発・承認から市販後へ向け一貫したリスクマネジメントの試み

田原浩一郎\*, 前中 孝夫\*, 橋本 順一\*\*

**Sunitinib: From Industry,  
A New Approach to Safety Risk Management Throughout  
the Drug Life Cycle from Clinical Development to Post Marketing Approval**

Koichiro TAHARA\*, Takao MAENAKA\* and Junichi HASHIMOTO\*\*

**Summary**

As simultaneous global drug development becomes more common, especially in the area of anti-tumor agents, consistent safety risk management through development to post-marketing is increasingly important. Risk management can be defined as the comprehensive and proactive application of scientifically based methodologies to identify, assess, communicate, and minimize risk throughout a drug life cycle so as to establish and maintain a favorable benefit/risk profile in patients and to confirm an appropriate benefit/risk balance. Pfizer Japan has adopted a sequence of procedures that comprehensively and proactively link the three steps of risk minimization action plans. Firstly, a safety review plan (SRP) is prepared and conducted at the stage of clinical studies. Secondly, a risk management plan (RMP) is formulated at the stage of new drug application. Then, finally, a pharmacovigilance plan is developed for the post-marketing stage.

For sunitinib, which inhibits multiple receptor tyrosine kinases, a pharmacovigilance plan had been developed following these steps; however, the regulatory review identified several issues to be addressed. Thus, it is important to encourage science-based discussions relating to pharmacovigilance. Actions regarding post-marketing safety monitoring procedures, such as the need for surveillance of all cases and/or distribution management, should be discussed in depth at an early stage of regulatory review. In addition, it seems to be a key issue to build a comprehensive risk management system to continuously confirm the effectiveness of risk minimization actions. From an early stage of drug development, industry, government, and academia should be required to work closely in order to plan, execute, and check the risk management system, taking account of actual medical practices in Japan.

**Key words**

Safety review plan, Risk management plan, Oncology, Sunitinib