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国内の現状：新医薬品等の承認後の制度と製造販売後臨床試験の実施の実態について*6

鈴木　英明*1,2，高橋　真二*1,3，安喜　孝行*1,4，大瀧　　明*1,5

Current Status in Japan of the Drug Re-examination System after the Approval of New antineoplastic Drugs, etc. and Implementation of Post-marketing Clinical Trials*6

Hideaki SUZUKI*1,2, Shinji TAKAHASHI*1,3, Takayuki AKI*1,4 and Akira OOTAKI*1,5

Summary

In Japan, the use of newly approved drugs, etc. is monitored under the Drug Re-examination System provided by the Pharmaceutical Affairs Law during a specified period of time (re-examination period), and the surveys and clinical studies to be performed during that period are laid down by the Ordinance for Good Post-marketing Study Practice (GPSP). Surveys based on the Ordinance for Good Vigilance Practice (GVP) are also conducted during the early post-marketing phase. After the completion of the re-examination period, drug re-examination approval is applied for based on the obtained data, so that the regulatory authorities can re-confirm drug efficacy and safety. In particular, post-marketing clinical studies for antineoplastic drugs are performed in accordance with the Ordinance for Good Clinical Practice (GCP), as well as with the GPSP. A recent investigation on the implementation status of post-marketing clinical studies for antineoplastic drugs revealed that the studies were required to be performed as a condition for approval or instructed to be performed for 69.2% of 13 recently approved ingredients of antineoplastic drugs (new chemical entities: 6/9, extension of indications: 3/4). Overseas data were used as clinical data in the application dossier for 8/9 of the new chemical entities and 1/4 of the drugs with extension of indications. This investigation could not confirm the status of voluntary implementation of post-marketing clinical trials by pharmaceutical companies.

Key words

Drug's Re-examination System, Post-marketing Clinical Trials