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

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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 reconfirm 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