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最近の承認審査事例を踏まえた日本における新薬開発戦略
—ドラッグ・ラグの解消に向けて—

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Investigation of the Effectiveness of Recommended Strategies for Speeding up the Approval of New Drugs

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Summary

In order to shorten the lag time before approval of novel drugs (so-called drug lag) in Japan, various drug development strategies, including biomarker utilization, bridging strategy, foreign data, pharmacogenomics (PGx) and multi-national studies, have been recommended. However, their effectiveness remains to be established.

In this study, 133 public review reports for New Chemical Entities (NCEs) published by the Pharmaceuticals and Medical Devices Agency (PMDA) between 2005 and 2009 were examined to evaluate whether the introduction of these new development strategies has been effective. The mean period from New Drug Application (NDA) to Marketing Approval (MA) was significantly shortened from 30.1 months in 2005-2007 to 22.8 months in 2008-2009 ($p=0.02$). The mean drug lag during 2005 to 2009 ranged from 4.2 to 8.1 years with no statistically significant difference. However, the drug lag from 2008 to 2009 tended to be shorter for NCEs where biomarkers, bridging strategy, foreign data, PGx and multi-national studies ($p=0.08$) had been utilized, compared to those where these methods had not been employed.

Based on those findings, we conclude that flexible and combined utilization of the recommended methods may contribute to the improvement of clinical drug development by speeding up the approval of new drugs.

Key words

New Chemical Entity, Biomarker, Bridging strategy, Pharmacogenomics, Multi-national study, Clinical Development Plan, Drug Lag.