

Research on Anticancer Drug Approval Lag between
Japan and the United States by Indicated Cancer
Incidence

Kenji Yamashita

DP-16406

Department of Clinical Medicine (Pharmaceutical Medicine)

Graduate School of Pharmaceutical Sciences

Kitasato University

5-9-1 Shirokane, Minato-ku, Tokyo, 108-8641, Japan

Abstract

Recent reports have indicated that approval lag for anticancer drugs between Japan and the United States (US) has decreased. However, whether this is also true for drugs used to treat minor cancers remains unknown. In the present study, we aimed to analyze anticancer drug approval lag between Japan and the US based on cancer incidence (major vs. minor cancers). We also aimed to investigate factors that affect longer approval lag for anticancer drugs by examining development strategy utilized in Japan as well as expedited development programs utilized in the US Food and Drug Administration (FDA).

First, we analyzed anticancer drugs approved in Japan between 2006 and 2016 to compare the approval lag between Japan and the US based on cancer incidence (major vs. minor cancers). The lag of anticancer drugs for minor cancers was shown not to have decreased compared to that a decade ago. Development strategies resulting in longer approval lag were still employed by pharmaceutical companies more often for the development of drugs used to treat minor cancers than for those targeting major cancers, leading to a significant difference in the approval lag time between drugs for major and minor cancers. Secondly, for anticancer drugs approved in the US between 2012 and 2017, we investigated time from Investigational New Drug Application (IND) to approval by the

US FDA by cancer incidence (major vs. minor cancers), along with the information about utilization of the expedited development programs, orphan drug designation, and pivotal study design. Drugs targeting minor cancers more frequently utilized the expedited development programs (any of breakthrough therapy designation, accelerated approval and priority review) than those targeting major cancers. Breakthrough therapy designation, accelerated approval, and pivotal study design without comparator arm significantly contributed to expedited drug approval.

Here, we showed that the approval lag duration between Japan and the US for drugs targeting minor cancers has not diminished since 2006, indicating that shortening of the lag for the overall anticancer drugs was predominantly caused by drugs targeting major cancers. On the other hand, the time from IND to approval by the US FDA was not significantly different between drugs for major and minor cancers, which were approved between 2012 and 2017; its median was numerically shorter for drugs targeting minor cancers. In the US, drugs targeting minor cancers significantly more frequently utilized expedited development programs that lead to shorter time from IND to approval.

Effective measures to expedite the development of drugs targeting minor cancers in Japan should be implemented to shorten the approval lag time.