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Impact of the Action Program for Accelerating the Review of Medical Devices in Japan

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Summary

The "Action Program for Accelerating Review of Medical Devices" (AP) was announced by the Ministry of Health, Labour, and Welfare on 11th December 2008 with the aim of expediting the review process of medical devices by the Pharmaceuticals and Medical Devices Agency (PMDA), and came into force on 1st April 2009. We investigated whether the review period for medical devices was shortened after introduction of the AP. We also compared the number of man-days required for review of each application in order to assess whether the efficiency of review was improved after introduction of the AP.

Methods: Applications submitted between 1st April 2004 and 31st March 2012 were extracted from the database of the Japan Association for the Advancement of Medical Equipment (JAAME Search). We excluded applications for partial change, for original products under post-market surveillance, or for product name change, leaving 109 applications.

We conducted simulations using Fisher's permutation test with 1 million random samplings to compare the mean values of the estimated review days before and after introduction of the AP, and we similarly compared the estimated number of man-days required for the review of each application before and after the AP.

Results: (1) Introduction of the AP significantly shorted the review period to 76% of that before the AP ($p<0.01$). (2) There was no significant difference between the mean number of man-days required for review before and after the AP.

Conclusion: The review period was significantly shortened after introduction of the AP, but the number of man-days required for review of each application was unchanged. Therefore, the shortening of the review period can be explained by the increase in the number of reviewers.

Key words

Medical Device, Review Period, MHLW, PMDA, Action Program, Man-days, Japan