عنوان مقاله:

Development Time and Patent Extension for Prescription Drugs in Canada : A Cohort Study

محل انتشار:

مجله بین المللی سیاست و مدیریت بهداشت, دوره 10, شماره 8 (سال: 1400)

تعداد صفحات اصل مقاله: 5

نویسنده:

Joel Lexchin - School of Health Policy and Management, York University, Toronto, ON, Canada

خلاصه مقاله:

The Comprehensive Economic and Trade Agreement between Canada and the European Union provides for an extension of Canadian patents for prescription drugs by up to ۲ years. One of the arguments advanced for longer patent time is to compensate companies for the length of the overall drug development time (the time between patent application and market approval). This study investigates overall development time in Canada for different groups of drugs approved between January ۱, ۲۰۰۹ and December ۳۱, ۲۰۱۸ and how many of these drugs are eligible for up to ۲ years of patent term extension. Based on a list of patents and dates of market approval, the change in overall development time for all drugs was calculated along with whether there were differences in development time between different groups of drugs. Using Canadian patent filing dates, overall development time for all drugs went from a mean of ۲۲۴۰ days (۹۵% CI : ۱۸۳۲, ۲۶۴۸) in ۲۰۰۹ to ۴۱۹۷ days (۹۵% CI : ۳۷۲۸, ۴۶۶۵) in ۲۰۱۸ (analysis of variance [ANOVA], P < .۰۰۰۱). Using first global patent filing dates, overall development time went from a mean of ۴۴۸۱ days (۹۵% CI : ۳۰۵۳, ۵۹۰۸) in ۲۰۰۹ to ۶۲۹۸ days (۹۵% CI : ۴۸۳۹, ۷۷۵۶) in ۲۰۱۸ (ANOVA, P = .۰۱۱۸). There was a statistically significant difference in the overall development mean time between small molecule drugs (۳۵۵۳, ۹۵% CI : ۳۳۶۱, ۳۷۴۶) and biologics (۳۹۰۳, ۹۵% CI : ۳۵۹۵, ۴۲۱۲), (t test, P = .۰۴۸۷) when using Canadian patent filing dates but not when first global patent filing dates were used. There was no statistically significant change in overall development time among drugs that were substantial, moderate or little to none additional therapeutic value compared to existing drugs. Out of ۲۳۸ drugs, ۲۱۸ (۹۱.۶%) would have been eligible for patent term extension with ۱۹۵ (۸۰.۷%) eligible for the full ۲ years. Patent term extension does not appear to be justified based on changes in overall development time, except possibly in the case of biologics. There are also trade offs in terms of increased expenditures that need to be considered if patent terms are lengthened.

کلمات کلیدی:

Biologics, Canada, Development Time, Patent Term Extension, Small Molecule Drugs