Abstract: Pre-marketing authorization of new medical devices in the European Union and the United States

Abraham PS, Gholmie J, Seoane-Vazquez E, Rodriguez-Monguio R
Value in Health, Volume 16, Issue 3 , Page A267, May 2013

Massachusetts College of Pharmacy and Health Sciences University, Boston, MA, USA, University of Massachusetts, School of Public Health and Health Sciences, Amherst, MA, USA

OBJECTIVES: The European Union (EU) and the United States (US) have different regulatory systems for pre-marketing approval of medical devices (MDs) that result in differences in the MDs market authorizations and dates of market entry. This study analyzed differences between the MD regulatory systems in the US and the EU and evaluated the effect of those differences in pre-marketing authorization of new MDs in the period January 2000 to September 2012.

METHODS: The study included a comparison of the regulation of MDs in the EU and the US and an analysis of MDs pre-marketing authorization dates in both systems in the period January 2000 to October 2012. Data were collected from the US Food and Drug Administration (FDA), companies' webpages and a review of the literature. Descriptive statistics were used to compare differences in approval dates. Regression analysis was used to assess trends in differences in approval dates over the study period.

RESULTS: There were important differences in pre-marketing approval systems for MDs between the US and the EU. More clinical information was required for approval of MDs in the US than in the EU. The FDA listed 514 new MDs approved in the study period. FDA premarketing authorization and EU pre-marking authorization (i.e. CE mark) dates were available for 201 MDs. Approval of MDs occurred on average ± stdev 2.57±3.79 years earlier in the EU than in the US (median=2.42 years; 95%CI=1.86- 3.29 years). Overall, 171 MDs (85.1%) were authorized first in the EU. The difference in authorization dates grew over the study period at a rate of approximately 2.5 months per year.

CONCLUSIONS: The EU and the US have different safety and efficacy regulatory requirements for MDs pre-marketing authorization. European patients have early access to new devices, whereas US patients have more MD-related information available for reimbursement and clinical decisions.