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Have FDA expedited programs really shortened drug review time? an analysis of newly approved therapies and how FDA expedited programs have impacted drug development timelines

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In attempt to encourage innovative drug development, the FDA has developed four approaches to expedite the drug approval process. These four approaches include Fast Track, Breakthrough Therapy, Accelerated Approval and Priority Review. Fast Track was introduced to accelerate the approval of medications for serious conditions and to fulfill unmet medical need. Accelerated Approval is a pathway that permits medications for serious conditions that fulfill unmet medical need to receive approval based on a surrogate endpoint. Priority Review is designated for medications that when they get approved they will bring significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. Breakthrough therapy designation is a novel pathway introduced in 2012. Breakthrough therapy designation is a process intended to treat serious or life threatening disease and the approved drug may demonstrate significant advantage over the available therapies. The objective of the research was to identify which of the expedited programs shorten development time and which products and classes benefit the most. It was analyzed new molecular entities that have been approved over the last 6 years (2009-2014). The entities were categorized by therapeutic area, line of therapy and mechanism-specific order of entry. Then it was evaluated whether the new entities had utilized one or more of the expedited programs, and whether the expedited program shortened the time from IND to regulatory approval.

Biography

Krasimira Pekova is a licensed pharmacist with extensive experience in the healthcare industry in Europe and United States. She holds a pharmacy degree from Bulgaria and Master of Science in Regulatory Affairs of Drugs, Biologics and Medical Devices from Northeastern University, Boston. She is an Analyst with Artisan Healthcare Consulting, where she provides market access insights to global brands. She analyses the oncology global market access repository, a compilation of regulatory, health technology assessment, and reimbursement decisions for oncology products in the 15 largest markets worldwide.

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