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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 programs to expedite the drug approval process for innovative or potential high-impact therapies. These four approaches include FastTrack, Breakthrough Therapy, Accelerated Approval and Priority Review. FastTrack 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 intended to treat serious or life threatening disease. The objective of the research was to identify which of the expedited programs have truly shortened drug development time and which drugs and therapeutic areas have benefited the most from these programs. We analyzed new molecular entities that have been approved over the last 6 years (2009-2014) and determined which programs each entity was granted as they underwent regulatory review. We categorized the entities by therapeutic area, line of therapy and mechanism-specific order of entry. We then measured whether the expedited program the drug was granted had truly shortened the time from IND to regulatory approval.

Biography

Krasimira Pekova is a licensed pharmacist with 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, MA. Krasimira Pekova 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. Artisan Healthcare Consulting is a management-consulting firm that provides strategic insights to healthcare product companies.

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