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Variation in the availability of cancer drug generics in the United States of America

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Abstract

While most of the attention and spending in the oncology community in the United States has been focused on the remarkable scientific inventions of the newer targeted drugs, the shortage of the older essential cancer drugs that are off patent, mostly generics and injectables, has a threatening impact on the health of cancer patients, the execution of clinical trials and the identification of newer drugs and thus impacts upon the burden of costs and pressures on the health system in the United States. It is a part of the problem of the scarcity of generics across all medical specialties, but its oncology is particularly vulnerable. The problem in The United States has been increasing since the beginning of the 21st century until the 2011; since then there has been some improvement in 2012 and the first two quarters of 2013. In the second quarter of 2012, there were 211 active shortages, down from 246 reports of active shortages in the same quarter of 2011. The Food and Drug Administration (FDA) officials ascribe the improvement to efforts that the agency made after President Obama issued an executive order in 2012 that impel the FDA to obtain early reports from companies about potential shortages. The drivers of the shortages are multi-factorial. But are largely economic and are due to the lack of incentives to produce generics. There are efforts from the US government, politicians and the medical, pharmacy and oncology communities. However, the problem is still serious. There is a general agreement that efforts so far have not been adequate, and that there is a need for addressing effectively the fundamentals and the underlying causes. There is a lot that could be done in the United States and across the world to improve the accessibility of economically sustainable better value cancer drugs regardless of whether they are brand or generics and aiming at a win–win outcome for all stakeholders.

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