Drug Des Devel Ther. 2016 Jun 30;10:2109-17.

Clinical implications for substandard, nonproprietary medicines in multiple sclerosis: focus on fingolimod.

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Abstract

Both proprietary and nonproprietary medicines are expected to undergo rigorous preapproval testing and both should meet stringent health authority regulatory requirements related to quality to obtain approval. Nonproprietary (also known as copy, or generic) medicines, which base their authorization and use on the proprietary documentation and label, are often viewed as a means to help lower the cost and, thus, increase patient access. If these medicines fail to meet quality standards, such as good manufacturing practice and bioequivalence (in humans), they are then defined as substandard copies and can pose serious risks to patients in terms of safety and efficacy. Potentially noncontrolled or different manufacturing process and excipients in nonproprietary medicines may result in poor batch-to-batch reproducibility (accurate and consistent quantity of each ingredient in each capsule/tablet) and lower quality. Substandard, nonproprietary copies of medicines that are immunomodulatory or immunosuppressive are of concern to patients due to their possible untoward safety and lack of efficacy events. This article reviews the potential risks associated with nonproprietary medicines that do not meet the regulatory requirements of the United States Food and Drug Administration, the European Medicines Agency, or the World Health Organization. The clinical implications for patients are described. This article focuses on nonproprietary medicines for multiple sclerosis, particularly fingolimod, that are not identical to proprietary versions and could thus fail to meet efficacy expectations or have different impact on the safety of patients with multiple sclerosis.