Generic Competition and Authorized Generics in the US

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Introduction

A new drug application authorized generic (AG) has the same active and inactive ingredients as the brand but is "marketed, sold, or distributed directly or indirectly to retail class of trade with either labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark that differs from that of the listed drug".

Since authorized generics contain the same active and inactive ingredients as the branded drug approved by the initial NDA, the safety and efficacy profiles are considered identical. Authorized generic compete in the market with generic products approved by other companies.

No recent studies have analyzed trends in the market of authorized generic drug.

Objectives

We assessed trends in the marketing of authorized generics in the US in the period 1982-November 2014.

Methods

To derive an NDC list for products (and corresponding dates for marketing intervals) classified as brand, authorized generic, and other generic, we first extracted information about authorized generics from the FDA List of Authorized Generic Drugs and the National Drug Code database. We then identified the NDA and ANDA numbers that match the information for each NDC number with the regulatory information contained in the Orange Book and the Drugs@FDA databases.

Time trends in generic marketing were described and compared with chi-square tests.

Results

Figure 1: Active Ingredients, Forms and Strengths Listed by the FDA in November 2014

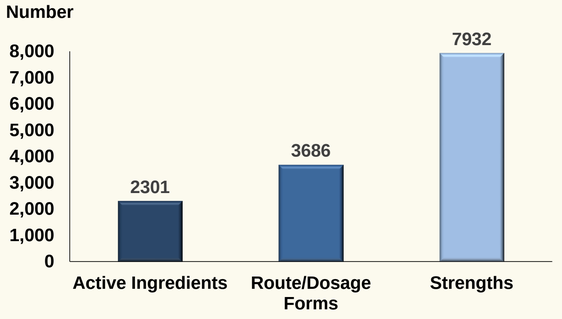


Figure 2. Market and Generic Status of Active Ingredients, Listed by the FDA in November 2014

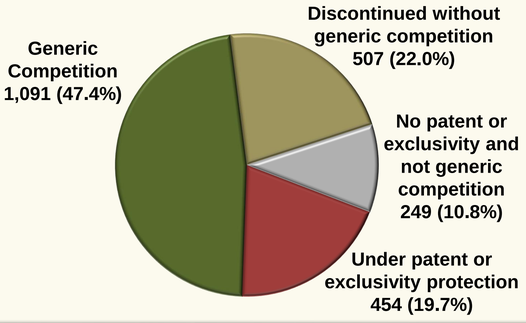


Figure 3: Authorized Generics Marketed for Active Ingredients, Forms and Strengths Listed by the FDA in November 2014

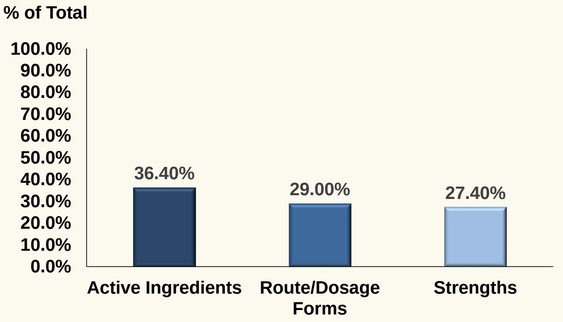
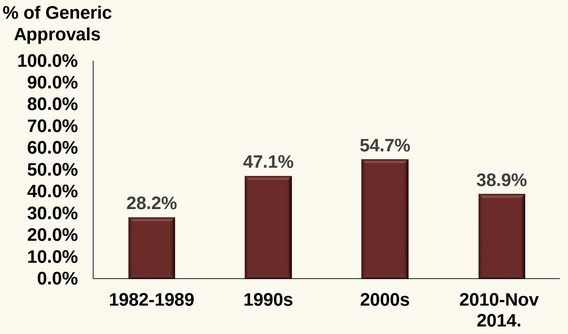


Figure 4: Trends in Authorized Generics Marketed for Active Ingredients by Generic Approval Year



In November 2014, the FDA listed 2301 approved active ingredients and combinations, with 3686 route/dosage forms and 7932 strengths (Figure 1).

By November 2014, 47.4% of FDA approved active ingredients and combinations had generic competition, 22.00% were discontinued without generic competition, 10.8% did not have patent or exclusivity protection and did not have generic competition (Figure 2).

By November 2014, 19.7% of the active ingredients and combinations were under patent or exclusivity protection according to the information provided by the FDA's Orange Book.

There were 296 generic drugs approved before 1982, 195 in 1982-1989, 140 in the 1990s, 285 in the 2000s, and 175 in 2010-Nov 2014.

A total of 36.4% of the active ingredients/combinations with generic competition had at least one AG. AGs were marketed for 29% of the route/dosage forms and 27.4% of the strengths with generic competition (Figure 3).

The percentage of active ingredients/combinations with generic competition and AG significantly increased from 15.5% before 1982, to 28.2% in 1982-1989, 47.1% in the 1990s, and 54.7% in the 2000s, and 38.9% in November 2014 ($p<0.05$) (Figure 4).

Discussion

Our research indicates that the marketing of authorized generic drugs significantly increased over time. However, the marketing of authorized generic declined in the period 2010-Sep 2014 in comparison with the 2000s.

Originator pharmaceutical companies may decide not to market an authorized generic and use instead alternative market strategies such as "pay-for-delay" agreements with generic companies and providing substantial rebates to third party payers to reduce the impact of generic competition in the originator brand market share.

Further studies could investigate the causes behind the trends in the approval and marketing of authorized generic drug in the US.

Conclusions

A significant percentage of generic drugs experienced the entrance of an authorized generic. The use of authorized generics increased overtime.

The effect of authorized generics on the generic market and the incentives for generic entry should be assessed.

Acknowledgment

Funding for this work was made possible, in part, by the Food and Drug Administration through grant 1UO1FD005272-01. Views expressed here do not necessarily reflect the official policies of the Department of Health and Human Services; nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.