IMS INSTITUTE FOR HEALTHCARE INFORMATICS

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Price Declines after Branded Medicines Lose Exclusivity in the U.S.

Introduction

When novel medicines lose exclusivity in the United States, competitors quickly enter the market and bring about rapid decreases in price. With the world's highest generic efficiency rate – the extent to which patients switch from the brand to a generic medicine following loss of exclusivity – the U.S. healthcare system captures maximum cost benefit from these events.

In previous reports, such as *Medicine Use and Shifting Costs: A Review of the Use of Medicines in 2014*, we measured the share of total prescription volume represented by generic medicines and the impact of patent expiries on aggregate spending.

The purpose of this healthcare brief is to document the changing price of medicines as generics enter the market. While the public discourse and debate are focused on the issue of rising drug costs, we take this opportunity to highlight the reduction in prices associated with the use of generic medicines.

The study was conducted by the IMS Institute with funding support from the Pharmaceutical Research and Manufacturers of America (PhRMA). The contributions to this healthcare brief of Lauren Caskey, Bernie Gardocki, and Michael Kleinrock are gratefully acknowledged.

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Methodology

This study measures price declines following loss of exclusivity for every medicine that first became available as a generic between 2002 and 2014.

Sales data was obtained from the IMS National Sales Perspectives (NSP)™, a near census level audit of the U.S. pharmaceutical market. Prices in the audit are best thought of as the average invoice price of a product prior to the negotiation of off-invoice discounts and rebates. The average invoice price is typically lower than the list price, but higher than the net price.

This study compares the price of each branded medicine in the year prior to loss of exclusivity to the average price of all generics of the same molecule and formulation on the market in the months that follow. The average price reduction for each cohort is weighted by the pre-expiry sales of each branded medicine. Changes in volume after loss of exclusivity are not taken into account.

Price reductions in the ten year analysis are measured at twelve month intervals for 428 products with at least twelve months of generic sales history.

Oral medicines were grouped into four cohorts based on generic entry year in the monthly analysis, which includes 302 products with at least four months of generic sales history. Some medicines in the 2011-2013 cohort have less than 36 months of generic sales data. One medicine, clopidogrel, is included in both the 2005-2007 and 2011-2013 cohorts due to the brief availability of generics six years prior to the brand's loss of exclusivity in 2012.

Key Findings

Generic drugs greatly reduce the price of medicines. Generics enter the market at substantially lower prices than the brands for which they are substituted, and their prices continue to fall in subsequent years. This creates savings for patients, payers, and the healthcare system as a whole.

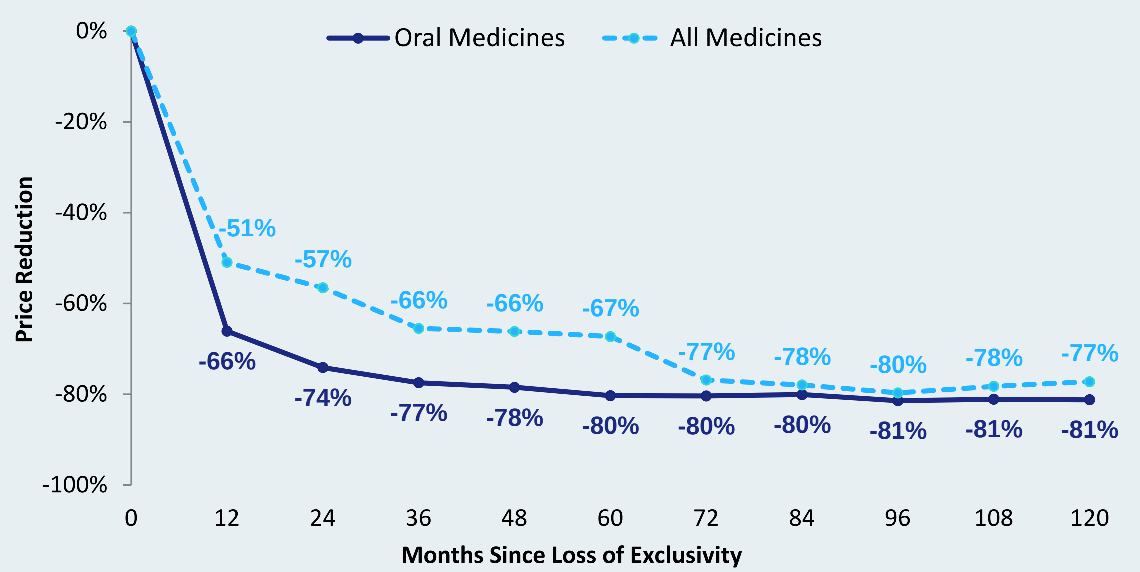
Generics that entered the market between 2002 and 2014 reduced the price of medicines by 51% in the first year and 57% in the second year following loss of exclusivity. Prices of oral medicines were reduced further, by 66% in the first year and 74% in the second year after generic entry. Within five years, prices of generic oral medicines fell to 80% from their pre-expiry brand prices.

Over the last decade, oral generic medicines have reduced prices more rapidly and to a greater extent. Oral generics that entered the market between 2011 and 2013 had prices 74% lower than pre-expiry brand prices within 8 months of becoming available, compared to only a 36% reduction for 2002 to 2004 expiries. Prices were 90% lower within 2.5 years for oral generics in the most recent group of expiries. Immediate savings in the first month of generic availability has also accelerated, with 46% lower prices in the first month compared to reductions of only 36% for oral generics that entered the market between 2002 and 2004.

The slope of the monthly price reduction line for generics reflects the number and price levels of competitors in the market following the original brand's loss of exclusivity. In some cases, a generic manufacturer is granted a 180-day exclusivity period, after which more manufacturers typically enter the market. This typically results in a price reduction line that plateaus for the first six months before declining further.

Generic drugs enter the market at lower prices than the brands they replace, and their prices continue to decline

Monthly Price Reductions after Loss of Exclusivity



Source: IMS Health, National Sales Perspectives, March 2015

- The immediate price reduction following generic entry is substantial, and is followed by continued savings in subsequent years.
- Twelve months after generic entry, prices of oral generic medicines drop 66%.
- Oral generic prices are 74% lower than pre-expiry brand prices after two years.
- Price reductions occur faster for oral medicines than for injectable drugs, which often attract fewer generic competitors.
- After six years, the price reductions for injectable medicines are nearly equal to the price reductions for oral medicines.
- Oral generics cost 80% less than the brands they replace within five years.
- Many patients benefit from the availability of low cost medications, as 88% of all prescriptions are dispensed as generics.

Chart note: Includes 428 medicines with at least twelve months of generic sales data, of which 288 are oral medicines.
Price Declines after Branded Medicines Lose Exclusivity in the U.S. Report by the IMS Institute for Healthcare Informatics.

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