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THE EFFECTS OF GENERIC COMPETITION ON DRUG PRICES OVER TIME

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Competition generally lowers prices for medicine, but the amount and timing of the price changes will depend upon a number of factors. In general, the larger the market and the greater the number of entrants, the faster prices will fall. The efficiency of the domestic distribution sector is important. Measures that make markets more efficient are rules to permit/require easy substitution of generic versions by pharmacies, labeling laws that educate consumers (and physicians) of generic names, and efficient and ethical incentives to physicians and third party reimbursement agents. External factors are also important, and in particular, the existence (or non-existence) of a competitive market for generics in foreign countries.

When patents no longer constrain generic entry in the domestic market, it is still necessary for the generic producers to invest in the engineering and marketing costs associated with bringing a generic product to market. These are not trivial for a novel product. Generic entry into the South African, European or North American markets have been generally expedited by the fact that India and other significant developing country markets are now without product patents, and developing country generic producers were able to provide a ready source of generic active pharmaceutical ingredients (APIs) or manufactured bulk medicines. However, this has not been true of products for which there was not a sufficient market in India and other developing countries, and it will not generally be the case in the future, as India and other generic producers are required to adopt product patents.²

The factors that will determine the timing of price decreases from generic competition include:

- (a) the rate that generic suppliers can learn how to manufacture the drug and satisfy regulatory requirements for registration
- (b) the time needed to improve efficiency of manufacturing processes,
- (c) the number of generic competitors that enter the market,
- (d) the rate of market penetration in order to achieve efficient scale economies.

¹ Iris Boutris and Yonathan Haregot contributed the research on Maryland Medicaid reimbursements.

² And to some extent may be constrained by TRIPS restrictions on exports of medicines manufactured under compulsory licenses.

Brazil

One important case of generic entry concerns Brazil. In 1996 Brazil became the first economically significant purchaser of generic ARV APIs and bulk products. By 1997 Brazil was providing HAART treatment. Initially the generic prices (either locally manufactured or imported) were not significantly lower than the brand name/patent owner prices, but over time, generic prices fell significantly. In 1998 Brazil was paying more than \$25 thousand per kilo for the generic active ingredients for d4T and about \$20 thousand per kilo for 3TC APIs. By 1999 these prices had fallen to approximately \$8 thousand for d4T and \$5,000 for 3TC. By 2003 these prices were closer to \$500 per kilo. For ARV products facing competition in Brazil, the finished product costs have continued to fall every year.

AZT, ddI, 3TC, d4T, and nevirapine were among the ARV products not patented under Brazilian law, and thus the Ministry of Health was free to manufacture its own generic versions of these products or import them from foreign generic manufacturers. As the following table shows, generic competition reduced prices over time.³

Table 1: Price evolution (in US\$) of ARV for adult use with domestic production. Brazil, 1996 - 2001⁴

Drug	Unit Price US\$	1996	1997	1998	1999	2000	2001
Zidovudine (AZT) cap 100mg		0.56	0.53	0.45	0.21	0.18	0.15
Zidovudine + Lamivudine 300mg + 150mg tab		N.A.	N.A.	3.38	2.01	0.70	0.54
Didanosine (ddI) tablet 25mg		0.52	0.41	0.26	0.23	0.19	0.16
Didanosine (ddI) tablet 100mg		1.85	1.39	1.02	0.76	0.50	0.49
Lamivudine (3TC) tablet 150mg		2.90	2.70	2.39	1.51	0.81	0.34
Stavudine (d4T) cap 30mg		N.A.	1.75	1.03	0.46	0.21	0.19
Stavudine (d4T) cap 40mg		N.A.	2.32	1.02	0.64	0.27	0.27
Nevirapine tablet 200mg		N.A.	N.A.	3.02	3.02	1.28	0.34

³ Ministry of Health, Brazil, *National AIDS Drug Policy*, June 2001, <http://www.aids.gov.br/final/biblioteca/drug/drug6.htm>

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Thailand

A somewhat different experience from Thailand is also informative. Pfizer was able to maintain a monopoly on fluconazole sales under non-patent regulatory barriers to entry, and was charging 200 Baht per pill in 1998. When the Thai government allowed generic competition, several generic firms entered the market, and prices fell to 6.5 Baht in nine months. The more rapid decrease in prices was in part feasible because there was already a competitive market for generic fluconazole outside of Thailand, and firms could easily import inexpensive APIs or bulk product for sale in Thailand.

United States of America

The PRIME Institute of the University of Minnesota has compiled data on generic penetration of the brand market in pharmaceuticals. According to their analysis, for most products, the best generic price was obtained about thirty months after the first generic entry into the market. In the Prime Institute analysis, the generic products entered the market about 27 percent below the brand price, and prices fell over time. After 30 months, generic prices were approximately 20% of the brand price.⁵

Maryland Medicaid reimbursements

The Consumer Project on Technology (CPTech) has analyzed reimbursement data from the Maryland Medicaid program for drugs that went off patent in the U.S.A. in 1996. In Table 2 the data show that over six years, generic competition achieved a mean reduction of nearly 60% for the three drugs selected, but the savings were quite different for each product. The decrease for Clozapine was only 25 percent, for Estradiol it was 61 percent, and for Ranitidine the price dropped by 93 percent.

There were also significant differences in the timing of price changes. The price of Ranitidine achieved most of its per unit savings in 1999, which is consistent with the Prime Institute analysis that on average, the best price is found after 30 months of generic competition. Clozapine prices had their largest drop in 2000, and are still falling. And the price for Estradiol dropped by half in 2002, six years after the patent had expired. Thus, averages can be misleading, and for particular products, both the size of the generic savings and the timing of price decreases will vary considerably.

⁵ Stephen W. Schondelmeyer, *The Role of Generics in the U.S. Pharmaceutical Market*, Presentation to the World Bank. June 24, 2003. Compiled by the PRIME Institute, University of Minnesota from data found in Kidder, Peabody.

Table 2: Price evolution in US\$ of Clozapine, Estradiol, and Ranitidine from 1996-2001⁶								
Unit price in USD								
Drug/Year	1996	1997	1998	1999	2000	2001	2002	Reduction in price
Clozapine 25mg	1.36	1.37	1.31	1.32	1.09	1.06	1.02	25%
Estradiol 1mg	0.36	0.27	0.16	0.24	0.25	0.24	0.14	61%
Ranitidine 150mg	1.56	0.63	0.26	0.12	0.11	0.11	0.11	93%

⁶ Maryland Medicaid Reimbursement data.