SPECIAL REPORT

Competitive effects on the generics industry

A study of the factors influencing generics makers' decision on whether to enter a specific market found that firm size, market revenue and expected competition all had an effect. Market size was also positively associated with the entry of more generics. The effect of a financial subsidy on generics entry was also investigated.

Keywords: Financial subsidy, generics entry, generics market, price competition

Prescription drug spending is estimated to have accounted for 16.7% of the US$2.7 trillion spent on healthcare in 2015.

In theory, an increase in the use of generics should help to reduce overall drug expenditures. However, growth in spending on medicines in the US increased by US$46.2 billion, or 12.2%, over 2014 levels, reaching US$425 billion in 2015 [1]. This increase comes despite a simultaneous growth in spending on generics, which increased by US$7.9 billion (7.4%) to US$114.1 billion in 2015.

One possible explanation for the increase in spending on medicines could be a lack of price competition between generics makers. This could be due to insufficient generics makers entering certain drug markets. A possible deterrent to entry could be the expected competition from other generics makers. This so-called 'competitive effect' is an important, however, complex factor for policymakers to understand. Competitive effects are challenging to identify, especially when considering that since markets with many generics makers (and therefore more competition) are usually profitable for many different reasons.

Mr Edward Kong, Research Assistant at the Yale University, Department of Economics, carried out a study into the factors that influence a generics maker's decision to enter a specific market [2].

The decision of whether to enter the market for a particular drug is complex and strategic, and the factors that influence firms' entry decisions are not fully understood. In the generics industry, larger markets have been documented to support more generics entrants. It has also been found that firms tend to enter markets for drugs that are similar to those for which they have previous experience. It has been estimated that experience in a drug market can reduce a firm's cost of entering a similar market in the future by 7% on average. This supports the hypothesis that specialization allows firms to mitigate the risk of over entry (a phenomenon where multiple firms enter the same market and all make reduced profits).

In his approach Mr Kong uses a static model of generics entry based on discrete-choice. His model assumes that firms only have incomplete information about their competitors and allows for firm heterogeneity. It includes market size as an important regressor and assumes that entry decisions are made simultaneously across firms in a 'one-shot game' for each market. The competitive effect is estimated in a discrete game model, which allows the importance of competition to be established relative to other factors such as market size.

Data on generics entry and revenue data for abbreviated new drug approvals (ANDAs) for high-revenue drugs approved between 2004 and 2014 was included in the analysis. Data was collected from the US Food and Drug Administration's (FDA) Orange Book, market revenue data from the Top 100 Drugs list from Drugs.com and firm revenue data.

The results showed that market size is positively associated with the entry of more generics. 'This effect is strong and robust to the inclusion of controls for the 'age' of the market and later new drug application (NDA) approvals.' The results showed that 'a 1% increase in sales predicts a significant increase of about three generics entrants (ANDAs), or equivalently, 11 drug products'. Mr Kong concluded that 'market size is an important predictor of generics entry'.

Factors affecting a generics maker's decision to enter a specific market were found to include firm size (measured as firm revenue), market revenue and expected competition (other generics entries). In fact, the effect of expecting an additional competitor was found to be similar to a US$540 million decrease in market revenues of the brand-name product.

Mr Kong found that 'the expectation of one additional competitor reduces the probability of entry by 10% on average'. On the other hand, a US$1 billion increase in market revenue increased the likelihood of a generics firm entering the market by 18.4% on average.

The effect of a financial subsidy on generics entry was also investigated. In the US the 180-day period of exclusivity carries a significant financial incentive, as it allows the generic drug to temporarily operate as a duopoly with the brand-name drug. Consequently, according to Mr Kong, many firms seek 'Paragraph IV' entry.

Mr Kong found that when using his discrete game model, giving a subsidy to all generics makers resulted in an increase in competition. 'With a subsidy, all firms have more incentive to enter, but they also realize that the equilibrium probability of competitor entry has also increased, which tapers the overall effect of the subsidy.' He also found that a fixed tax on entry, although reducing entry, also reduced competition, therefore having less effect on decreasing entry than expected.

Competing interests: None.

Provenance and peer review: Commissioned; internally peer reviewed.

Michelle Derbyshire, PhD, *GaBI Online* Editor

References

1. GaBI Online – Generics and Biosimilars Initiative. Spending on medicines in the US increases again in 2015 [www.gabionline.net]. Mol, Belgium: Pro Pharma Communications International; [cited 2016 Sep 29]. Available from: www.gabi-online.net/Reports/Spending-on-medicines-in-the-US-increases-again-in-2015
2. Kong E. Estimating competitive effects in firm entry with applications in the generic pharmaceutical industry. Yale University Department of Economics; 3 April 2016.

DOI: 10.5639/gabij.2016.0503.037

Submitted: 27 September 2016; Revised: 29 September 2016; Accepted: 3 October 2016; Published online first: 17 October 2016