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**SUBSTITUTION POLICY AND GENERIC
COMPETITION**

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Substitution Policy and Generic Competition

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March 2019

Abstract

I model the market for an active ingredient (with a brand-name drug and n differentiated generic versions) to study the effect of a substitution rule on prices and the extensive and intensive margin of generic competition. Both substitution rules with physician and patient veto decrease the brand-name price and shift market shares from the brand-name drug to the generics. A substitution rule with physician (patient) veto increases (decreases) generic prices and increases (decreases) the number of generic firms.

JEL classification: I18, I11, L50

Keywords: substitution rule, generic competition

1 Introduction

In this paper, I model a market for an active ingredient to study the effect of a substitution rule with physician veto or patient veto on drug prices and the extensive and intensive margin of generic competition.

Several European countries have implemented substitution policies to increase the use of generics (Kanavos et al. 2008). For instance, in Sweden, pharmacists are required to substitute the prescribed drug for a generic when neither physician nor patient opposes it (Granlund, 2010). Moreover, prescribing by international nonproprietary name, budgeting drug expenditure, and price dependent copayments aim at promoting generics.

Typically, physicians or patients may veto substitution, as generic substitution may be limited or not possible for critical dose drugs, which are characterized by narrow therapeutic ranges and/or serious consequences of under-/overdoses.

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The literature on the effect of substitution policies has mainly focused on the effect on drug prices, finding that substitution policies may reduce drug prices: In Sweden, a substitution reform has reduced drug prices on average by 10% (Granlund, 2010) through increasing market transparency (Granlund & Rudholm, 2011) and the effect of therapeutic competition (Granlund & Köksal-Ayhan, 2014). Also in Finland, a substitution reform has reduced drug prices by more than 10% (Aalto-Setälä, 2008) by making firms change their pricing strategy (Hokkanen et al., 2012).

2 Model

Consider a pharmaceutical market with two drug types $j = b, g$, an off-patent brand-name drug b and n corresponding generic versions $g(i)$, $i = 1, \dots, n$. Generic producers enter the market at fixed cost f .

The market is represented by a Salop circle with circumference 1 and a uniform distribution of patients. Generic firms $g(i)$ are located equidistantly on the perimeter of the circle; the brand-name producer is located in the center ¹.

Drug types are vertically and horizontally differentiated: Differences in gross valuation may stem from brand-biased consumers (Frank & Salkever, 1992) or lower quality perception of generics (Gaither et al. 2001). Based on their location x on the circle, patients prefer one of the generic versions vis-a-vis the others due to differences in product names, packaging or excipients (binders, coating, fillers etc.) and incur mismatch cost t for deviations from the ideal version.

Patients copay a fraction $\gamma \in (0, 1)$ of the drug price.

The utility of a patient who is located at x and buys a drug is

$$U(x) = \begin{cases} v - c_b & \text{if buying the brand-name } b \\ \theta v - t|x - z(i)| - c_{g(i)} & \text{if buying the generic } g(i) \end{cases}, \quad (1)$$

where v denotes gross valuation for drug type j , $\theta \in (0, 1]$ is the quality degradation for generics, c_j is the copayment for drug type j and $t|x - z(i)|$ is mismatch cost for buying $g(i)$ at $z(i)$.

Ex-ante, patients do not know their location on the circle, but can learn it from visiting a physician. Consider two type of physicians. H-types are perfect agents for patients and are able to identify the exact location x of patients. They may prescribe either the brand-name or a generic version. Assume that H-type physicians reveal this

¹This set-up follows Madden & Pezzino (2011).

information on location to patients. L-types lack skills to identify the patient's location and prescribe the molecule. Patients who see L-types physicians are prescribed the brand-name or one of the generic versions with equal probability. Assume that the share of L-type physicians is λ .

The (informed) patient indifferent between the brand-name drug b and the most preferred generic version $g(i)$ is given by $\hat{x} = \frac{c_b - c_{g(i)} - v(1-\theta)}{t}$.

Firms produce at constant and identical marginal cost, which is normalized to zero. Profits are

$$\pi_b = p_b q_b, \pi_{g(i)} = p_{g(i)} q_{g(i)} - f. \quad (2)$$

In the first stage, the regulator may implement a substitution policy, either with physician or patient veto. In the second stage, generic firms decide whether to enter the market. In the third stage, firms compete in prices.

3 Results

3.1 Coinsurance

Consider first a scenario with coinsurance as a benchmark. Demand for the brand-name is $q_b = (1 - \lambda)(1 - n2\hat{x}) + \frac{\lambda}{2}$; demand for the generic version i is $q_b = (1 - \lambda)(1 - n2\hat{x}) + \frac{\lambda}{2}$ and $q_{g(i)} = (1 - \lambda)2\hat{x} + \frac{\lambda}{2n}$. Equilibrium prices, quantities, and the generic market share are in Table 1.

	Brand-name	Generic
Prices	$p_b = \frac{t(4-\lambda)+4nv(1-\lambda)(1-\theta)}{12n\gamma(1-\lambda)}$	$p_{g(i)} = \frac{t(2+\lambda)-4nv(1-\lambda)(1-\theta)}{12n\gamma(1-\lambda)}$
Quantity	$q_b = \frac{t(4-\lambda)+4nv(1-\lambda)(1-\theta)}{6t}$	$q_{g(i)} = \frac{t(2+\lambda)-4nv(1-\lambda)(1-\theta)}{6nt}$
Generic Market Share		$Q_g = \frac{t(2+\lambda)-4nv(1-\lambda)(1-\theta)}{6t}$

Table 1: Coinsurance

The profit of a generic producer is $\pi_{g(i)} = \frac{(t(2+\lambda)-4nv(1-\lambda)(1-\theta))^2}{72n^2t\gamma(1-\lambda)} - f$. In a free-entry equilibrium, the equilibrium number of generic firms n is given by the highest integer number satisfying $\pi_{g(i)} \geq 0$.

A decrease in brand loyalty, i.e., a decrease in θ , decreases the brand-name price, while increasing generic prices. It increases the generic market share and the number of generic firms. An increase in the substitutability of generics, i.e., a decrease in mismatch cost t , decreases drug prices, increases the generic market share, but decreases number of generic firms.

3.2 Substitution Rule

3.2.1 Physician Veto

Consider now a substitution rule with physician veto. H-type physicians which may identify a patients' location may exempt patients from the generic substitution rule if lower gross valuation and/or higher mismatch cost outweigh the lower copayment for a generic. A physician veto does not affect copayments.

Demand for the brand-name is $q_b^\phi = (1 - \lambda)(1 - n^\phi 2\hat{x})$; demand for the generic version i is $q_{g(i)}^\phi = (1 - \lambda)(2\hat{x}) + \lambda \frac{1}{n^\phi}$. Equilibrium prices, quantities, and the generic market share are in Table 2.

	Brand-name	Generic
Prices	$p_b^\phi = \frac{t(2-\lambda)+2n^\phi v(1-\lambda)(1-\theta)}{6n^\phi \gamma(1-\lambda)}$	$p_{g(i)}^\phi = \frac{t(1+\lambda)-2n^\phi v(1-\lambda)(1-\theta)}{6n^\phi \gamma(1-\lambda)}$
Quantities	$q_b^\phi = \frac{t(2-\lambda)+2n^\phi v(1-\lambda)(1-\theta)}{3t}$	$q_{g(i)}^\phi = \frac{t(1+\lambda)-2n^\phi v(1-\lambda)(1-\theta)}{3n^\phi t}$
Generic Market Share		$Q_g^\phi = \frac{t(1+\lambda)-2nv(1-\lambda)(1-\theta)}{3t}$

Table 2: Substitution Rule – Physician Veto

The profit of a generic producer is $\pi_{g(i)}^\phi = \frac{(t(1+\lambda)-2n^\phi v(1-\lambda)(1-\theta))^2}{18(n^\phi)^2 t \gamma(1-\lambda)} - f$.

Under the substitution rule, patients who visit a L-type physician receive only generics, lowering demand for the brand-name and increasing demand for generics.

Compared to coinsurance, the substitution policy lowers the brand-name price and increases generic prices. The brand-name price decrease does not compensate lower demand, shifting market shares from the brand-name drug to generics. The increase in prices and quantities for generics result in higher profits, increasing the number of firms entering the market.

3.2.2 Patient Veto

Consider now a substitution rule with patients veto. If patients oppose substitution, they have to pay the difference between the generic price and the brand-name price. Copayments are $c_b^\psi = \gamma p_{g(i)}^\psi + p_b^\psi - p_{g(i)}^\psi$ and $c_{g(i)}^\psi = \gamma p_{g(i)}^\psi$. Patients who visit H-type physicians are informed about their location and buy the brand-name drug instead of a generic if the higher copayment is offset by higher gross valuation and/or lower mismatch cost.

Demand for the brand-name is $q_b^\psi = (1 - \lambda)(1 - n^\psi 2\hat{x})$, demand for the generic version i is $q_{g(i)}^\psi = (1 - \lambda)(2\hat{x}) + \frac{\lambda}{n^\psi}$. Equilibrium prices, quantities, and the generic market shares are in Table 3.

	Brand-name	Generic
Prices	$p_b^\psi = \frac{t(2-\lambda)+2n^\psi v(1-\lambda)(1-\theta)}{6n^\psi(1-\lambda)}$	$p_{g(i)}^\psi = \frac{t(1+\lambda)-2n^\psi v(1-\lambda)(1-\theta)}{6n^\psi(1-\lambda)}$
Quantities	$q_b^\psi = \frac{t(2-\lambda)+2n^\psi v(1-\lambda)(1-\theta)}{3t}$	$q_{g(i)}^\psi = \frac{t(1+\lambda)-2n^\psi v(1-\lambda)(1-\theta)}{3n^\psi t}$
Market Share		$Q_g^\psi = \frac{t(1+\lambda)-2n^\psi v(1-\lambda)(1-\theta)}{3t}$

Table 3: Substitution Rule – Patient Veto

The profit of a generic producer is $\pi_{g(i)}^\psi = \frac{(t(1+\lambda)-2n^\psi v(1-\lambda)(1-\theta))^2}{18(n^\psi)^2 t(1-\lambda)} - f$.

Similar to the substitution policy with physician veto, the substitution policy with patient veto decreases demand for the brand-name and increases demand for the generics. Moreover, the substitution policy with patient veto changes copayments, intensifying price competition between brand-name and generics. This decreases the brand-name price and generic prices.

As in the case of the substitution rule with physician veto, the substitution rule with patients veto shifts market shares from the brand-name drug to generics. For the generics, the increase in price competition and the corresponding decrease in prices decrease profits, decreasing the number of firms entering the market.

Proposition 1 summarizes the effect of the substitution rules on drug prices and generic competition:

Proposition 1 *Both substitution rules with physician and patient veto decrease the brand-name price and shift market shares from the brand-name drug to the generics. A substitution rule with physician (patient) veto increases (decreases) generic prices and increases (decreases) the number of generic firms.*

3.3 Welfare Analysis

As demand is inelastic, price changes are welfare neutral. A change in the number of generic firms affects welfare via two channels: First, a change in the number of firms affects mismatch cost; second, a change in the number of firms affects resources incurred for entry cost.

For patients, mismatch cost increase if they receive the brand-name drug under coinsurance but a generic under either substitution rule or a generic both under coinsurance and under the substitution rule with patient veto. Mismatch cost decrease if they receive a generic both under coinsurance and under the substitution rule with physician veto. Mismatch cost do not change if they receive the brand-name under both coinsurance and either substitution rule.

Market entry cost increase under the substitution rule with physician veto and decrease under the substitution rule with patient veto.

Proposition 2 summarizes the welfare effects of the substitution rules:

Proposition 2 *Both substitution policies increase mismatch cost for patients who receive the brand-name under coinsurance and a generic under either substitution policy and do not affect mismatch cost for patients who receive the brand-name under coinsurance and under either substitution policy. For all other patients, a substitution policy with physician (patient) veto decreases (increases) mismatch cost. A substitution policy with physician (patient) veto increases (decreases) market entry cost.*

4 Conclusion

Both substitution rules decrease the brand-name price and increase the generic market shares. While a substitution rule with physician veto increases generic prices and the number of generic firms, a substitution rule with patient veto decreases generic prices and the number of generic firms. This suggests a trade-off between price reductions and competition. Moreover, a substitution policy with physician veto may decrease mismatch cost for some patients, while a substitution policy with patient veto may result in higher mismatch cost. Mismatch cost may affect compliance or side effects.

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