The Impact of Pharmaceutical Regulation On Generic Competition

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Very Preliminary Version

Abstract

This paper studies the impact of a price cap and a reimbursement on generic competition in a Salop-type model following Madden & Pezzino (2011) with a brand-name drug and an endogenous number of differentiated generic versions. Both regulatory instruments reduce the generic market share as well as the number of generic competitors. Under the price cap, the generic market share and the number of generic competitors are maximized for a price cap equal to the unregulated brand-name price, i.e. no pricing restriction, and decrease with reductions of the price cap. Under the reimbursement limit, the generic market share and the number of generic competitors are maximized for a reimbursement of zero, i.e. no reimbursement, and decrease with increases of the reimbursement limit.
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1 Introduction

This paper studies the impact of a price cap and a reimbursement on generic competition in a Salop-type model following Madden & Pezzino (2011) with a brand-name drug and an endogenous number of differentiated generic versions.

Basically all European countries are confronted with rising health care spending, even outpacing GDP growth (Maynard & Bloor, 2003). Expenditure for pharmaceuticals represents a substantial and increasing proportion, varying roughly between 11.8%

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in the United Kingdom and 20.5% in Spain (OECD Health Data 2010). Main factors contributing to high spending are in addition to demographic factors and technology improvements pharmaceutical market imperfections such as agency imperfections, informational asymmetries and moral hazard, which create reduced price sensitivity on the demand side and a certain degree of market power on the supply side (Mossialos & Le Grand 1999, Hurley 2001).

As a consequence, most European countries have introduced regulatory instruments to contain public spending (Maynard & Bloor, 2003). On the supply side, price caps or price negotiations are intended to restrict monopoly pricing and reduce the prices of covered services. Maximum price systems, in which the regulatory body sets a price cap that can be charged for a drug, are applied in Austria, Belgium, Finland, France, Greece, Ireland, Italy, Norway, Portugal, and Spain (Danzon 1997; Espin & Rovira 2007).

Demand side instruments such as co-payments and reimbursement limits are intended to increase price sensitivity on the demand side. The reference price system, in which the regulator sets a ceiling for the amount reimbursable (reference price) for a group of pharmaceuticals (cluster), can be found in Belgium, Denmark, Finland, France, Germany, Greece, Italy, the Netherlands, Portugal, Spain, and the United Kingdom (Puig-Junoy 2010). In reference price systems, firms remain free to charge prices (Danzon 2001). If the manufacturer's price exceeds the reimbursement limit, the patient has to pay the difference between the market price and the reference price him/herself (Danzon 2001). That is, the reimbursement limit involves an additional copayment, which can be considered avoidable in the sense that purchasing a drug which is priced at or below the reference price does not involve the additional copayment (Lopez-Casasnova & Puig-Junoy 2000). The clusters, i.e. the group of pharmaceuticals, which the reimbursement limit applies to, are defined in terms of interchangeability (Lopez Casasnova & Puig-Junoy 2000). This can be understood in a chemical (drugs contain the same active ingredient), pharmacological (drugs belong to the same therapeutic category), or therapeutic (drugs have the same therapeutic function) way (Lopez-Casasnova & Puig-Junoy 2000).

In addition to influencing pharmaceutical prices directly, the substitution of higher-priced brand-name drugs by less expensive equivalents has been promoted. This might include generic versions of brand-name drugs. These may, however, differ in terms of binders, fillers, preservatives and density of packinging (Scherer 1996).

However, these two approaches may conflict. Pharmaceutical regulation may exhibit a trend of inhibiting competition by reducing generic entry (Danzon, Wang & Wang 2005). Thus, for a sustainable containment of pharmaceutical expenditure, not only price reductions but also high generic market shares and a sufficient degree of competition

are important. In addition, as substitutability among generics may be limited, a high number of generic competitors and thus generic versions is also desirable.

The paper most related to this is Brekke, Holmas & Straume (2010), who compare price cap regulation with reference pricing . Their model suggests that reference pricing induces stronger generic competition and lower brand-name market shares (Brekke, Holmas & Straume, 2010). With respect to price cap regulation, Brekke, Holmas & Straume (2010) find that a reduction of the maximum price reduces the generic market share, that is, stricter direct price regulation weakens generic competition. A study by the European Commission, which analyzes the prices of 122 active ingredients in 17 EU countries between 2000 and 2007, confirms that price cap regulation affects price competition negatively (European Commission, 2009).

However, the duopolistic market structure in Brekke, Holmas & Straume (2010) does not consider the competition and welfare effect of the number of generic competitiors. One the one hand, strong competition among generics (as opposed to competition between a brand-name and a generic) might contribute to price reductions. On the other hand, as substitutability among generic versions might be limited, a higher number of generic competitors may increase welfare, as it reduces consumer mismatch cost.

Against this background, this paper analyzes the impact of maximum price system (price cap) and a reference price system (reimbursement limit) on generic competition in a model following Madden & Pezzino (2011). Consumers are located around on the circumference of a Salop circle and may choose between a brand-name version of the drug (center of the circle) and one of n horizontally differentiated generic versions (on the circumference). The location of the firms captures objective differences between the brand-name drug and the generic versions, e.g. with respect to binders, fillers, preservatives, or a perception of generics as qualitatively inferior. Depending on their location on the circle, consumers have a preference for an ideal version of the drug, deviations from the preference for an ideal version cause mismatch cost. There are two types of patients: Price-conscious patients choose between the generic versions, brand-loyal patients choose between the brand-name drug and one of the generic versions. The number of generic firms is endogenous and, since each firm offers one version, corresponds to the number of generic versions available.

Both regulatory instruments reduce the generic market share as well as the number of generic competitors. Under the price cap, the generic market share and the number of generic competitors are maximized for a price cap equal to the unregulated brand-name price, i.e. no pricing restriction, and decrease with reductions of the price cap. Under the reimbursement limit, the generic market share and the number of generic competitors

are maximized for a reimbursement of zero, i.e. no reimbursement, and decrease with increases of the reimbursement limit.

The rest of the paper is organized as follows. The next section presents the Salop-type model with a brand-name drug and an endogenous number of generic competitors. Section 3 analyzes the benchmark case of no pharmaceutical regulation, the case of a price cap (maximum price system), and the case of a reimbursement limit (reference price system). Section 4 compares the regulatory scenarios with respect to the number of generic competitors. Section 5 concludes.

2 The Model

Using the Madden & Pezzino (2011)-extension of the framework of Salop (1979), consider a market for an active ingredient with a off-patent brand-name drug b and n corresponding, differentiated generic versions $g(i)$. The firms offering the differentiated generic versions $g(i)$ are located equidistantly around the perimeter of a unit circle, the firm providing the brand-name drug is located in the center of the circle.

All drugs contain the same active ingredient, but the generic versions differ in additives, dosage form, and bioavailability, which may limit substitution possibilities (Scherer, 1996). Based on their location on the circle, patients have a preference for one of the generic versions and incur mismatch cost for deviations from the ideal version. In addition, patients associate a higher quality with the brand-name as compared to any of the generic versions. The perception of the generics as qualitatively inferior is well documented (see Gaither et al., 2001 for a survey on the lower quality perception of generics) and may stem from price differences which are interpreted as quality indicator (Waber et al., 2008). Also uncertainty with uncertainty regarding product characteristics contribute to a lower willingness to pay for the generic (Schmalensee, 1982). The property of pharmaceuticals as experience goods, i.e. the difficulty of evaluating quality ex ante, and the risk of bad choices such as adverse side effects add to the uncertainty (Scherer, 1996). The perceived quality difference between the brand-name and the generic versions and the corresponding impact on utility will be captured by a differences in mismatch cost for the brand-name drug and the generic versions.

Similar to Brekke et al. (2008), there are two types of patients differing with respect to gross valuation of the drug. H-types have a higher valuation of the drug, they buy either the brand-name drug or the most-preferred generic version, trading off a higher perceived quality of the brand-name drug against a lower copayment for one of the generic versions. L-types are price-conscious patients with a lower valuation, they choose among

the generic versions, minimizing copayment and mismatch cost. Assume that the share of L-types is λ. Both types are uniformly distributed on the perimeter of the circle. A patient buys either one unit of the most preferred drug or not at all.

The utility of an H-type patient who is located at x and buys the brand-name version b located at the center, is given by

$$U = V - \delta - \gamma p_b, \tag{1}$$

where V denotes the gross utility from consumption for the H-type patient, δ denotes mismatch cost, γ is the coinsurance rate and p_b is the price of the brand-name version b. Health insurance reimburses a fraction $0 < \kappa < 1$ of the drug price, the remaining fraction $1 - \kappa = \gamma$ is paid by the patient. Thus, the effective price of the drug to the patient amounts to the proportion γ of the market price set by the manufacturer or intermediary (Zweifel et al., 2009).

The utility of an H-type patient who is located at x and buys a generic version $g(i)$ located at z_i, is given by

$$U = V - t\,|x - z_i| - \gamma p_{g(i)}, \tag{2}$$

where t denotes mismatch cost for deviations of the product's attributes from the patients' preferences, and p_{g_i} is the price of generic version g_i.

The utility of an L-type patient who is located at x and buys a generic version i located at z_i, is given by

$$U = v - t\,|x - z_i| - \gamma p_{g(i)}, \tag{3}$$

with $v < V$.

Differences in gross valuations across patients may result from socioeconomic differences, differences in willingness to pay for a brand-name, differences in risk aversion regarding the trial of substitutes, or differences in the severity of the condition or the level of suffering (see e.g. Brekke, Holmas & Straume, 2010).

The structure of the model can be summarized by the following two-stage game: In the first stage, potential generic competitors simultanously decide whether to enter the market for an active ingredient at fixed cost of entry f. Let n denote the number of generic entrants. The generic firms entering are located equidistantly around the circle. A firm offering a brand-name drug is already active in this market. In the second stage, firms compete in prices.

Production technologies exhibit constant marginal costs, which are normalized to

zero for simplicity. Profits are given as

$$\pi_b = p_b q_b,\ \pi_{g(i)} = p_{g(i)} q_{g(i)} - f. \tag{4}$$

Assume that fixed cost of entry f is sufficiently high:

$$f \geq f^{\min} = \frac{4\delta^2 (2-\lambda)}{t\gamma (4-\lambda)^2}. \tag{5}$$

This ensures that the firm offering the brand-name drug finds it profitable to serve the market also under generic competition.

3 Regulatory Scenarios

3.1 No Regulation

Consider first a system with no regulation as a benchmark.

The marginal H-type patient who is indifferent between purchasing the closest generic version i and the brand-name drug b is given by

$$V - \delta - \gamma p_b = V - t x_i^H - \gamma p_{g_i} \tag{6}$$

which yields

$$x_i^H = \frac{\gamma (p_b - p_{g_i}) + \delta}{t}. \tag{7}$$

Total demand for the generic version i from the H-segment is given by $q_i^H = 2x_i^H$. Total demand for the brand-name is given by $q_b = (1-\lambda)\left(1 - n 2 x_i^H\right)$.

The marginal L-type patient who is indifferent between purchasing the generic version g_i and the generic version g_j, is given by

$$v - t x^L - \gamma p_{g(i)} = v - t\left(\frac{1}{n} - x_i^L\right) - \gamma p_{g(j)} \tag{8}$$

which yields

$$x_i^L = \frac{\frac{t}{n} + \gamma\left(p_{g(j)} - p_{g(i)}\right)}{2t}. \tag{9}$$

Total demand for the generic version i from the L-segment is given by $q_i^L = 2x_i^L$. Thus total demand for the generic version i from both segments is given as $q_i = (1-\lambda) q_i^H + \lambda q_i^L$.

Firms' profits are given as

$$\pi_b = p_b\left(1-\lambda\right)\left(1-n2\frac{\gamma\left(p_b-p_{g(i)}\right)+\delta}{t}\right), \tag{10}$$

$$\pi_{g(i)} = p_{g(i)}\left(\left(1-\lambda\right)2\frac{\gamma\left(p_b-p_{g(i)}\right)+\delta}{t}+\lambda\frac{\frac{t}{n}+\gamma\left(p_{g(j)}-p_{g(i)}\right)}{t}\right)-f. \tag{11}$$

Equilibrium drug prices are

$$p_b = \frac{t\left(4-\lambda\right)-2n\delta\left(2-\lambda\right)}{4n\gamma\left(3-2\lambda\right)}, \tag{12}$$

$$p_{g(i)} = \frac{t\left(\lambda+1\right)+2n\delta\left(1-\lambda\right)}{2n\gamma\left(3-2\lambda\right)}. \tag{13}$$

Both drug prices decrease in the number of generic versions n, as more generic alternatives enhance competition.

The number of entering firms is determined by the zero-profit condition:

$$n = \frac{2\left(\lambda+1\right)\left(\Phi\left(3-2\lambda\right)+\Psi\delta\right)}{4\left(ft\gamma\left(3-2\lambda\right)^2-\Lambda\delta^2\right)}, \tag{14}$$

with $\Phi=\sqrt{ft^3\gamma\left(2-\lambda\right)}$, $\Lambda=\left(2-\lambda\right)\left(1-\lambda\right)^2$, and $\Psi=t\left(1-\lambda\right)\left(2-\lambda\right)$.

First stage equilibrium drug prices are given as

$$p_b = \frac{ft^2\gamma\left(3-2\lambda\right)\left(4-\lambda\right)-2\delta^2\Psi-\Phi\delta\left(\lambda+1\right)\left(2-\lambda\right)}{2\gamma\left(1+\lambda\right)\left(\Phi\left(3-2\lambda\right)+\delta\Psi\right)}, \tag{15}$$

$$p_{g(i)} = \frac{ft^2\gamma\left(3-2\lambda\right)+\Phi\delta\left(1-\lambda\right)}{\gamma\left(\Phi\left(3-2\lambda\right)+\delta\Psi\right)}. \tag{16}$$

The equilibrium quantity for the brand-name drug is

$$q_b = \frac{\left(1-\lambda\right)\left(ft^2\gamma\left(3-2\lambda\right)\left(4-\lambda\right)-2\delta^2\Psi-\Phi\delta\left(\lambda+1\right)\left(2-\lambda\right)\right)}{2t\left(ft\gamma\left(3-2\lambda\right)^2-\delta^2\Lambda\right)}, \tag{17}$$

the quantity for a single generic version is

$$q_{g(i)} = \frac{\left(2-\lambda\right)\left(ft^2\gamma\left(3-2\lambda\right)+\Phi\delta\left(1-\lambda\right)\right)}{\Phi t\left(3-2\lambda\right)+\delta\Psi}. \tag{18}$$

The total generic quantity is equivalent to the generic market share

$$Q_g = nq_{g(i)} = \frac{(\lambda+1)(2-\lambda)\left(ft^2\gamma(3-2\lambda)+\Phi\delta(1-\lambda)\right)}{2t\left(ft\gamma(3-2\lambda)^2-\delta^2\Lambda\right)}. \tag{19}$$

3.2 Price Cap

Now assume a price cap P, which limits the price charged by the brand-name producer. This is, the price cap is binding for the brand-name drug, but not the generic:

$$p_{g(i)} \leq P \leq p_b. \tag{20}$$

The number of firms is

$$n^{PC} = \frac{\lambda(\Phi(4-3\lambda)+2\Psi(P\gamma+\delta))}{ft\gamma(4-3\lambda)^2-4\Lambda(P\gamma+\delta)^2}. \tag{21}$$

First stage equilibrium drug prices are given as

$$p_b^{PC} = P,\ p_{g(i)}^{PC} = \frac{ft^2\gamma(4-3\lambda)+2\Phi(1-\lambda)(\delta+P\gamma)}{\Phi\gamma(4-3\lambda)+2\gamma\Psi(\delta+P\gamma)} \tag{22}$$

The equilibrium quantity for the brand-name drug is

$$q_b^{PC} = \frac{(1-\lambda)\left(ft^2\gamma(4-3\lambda)(4-\lambda)-2(2-\lambda)(\delta+P\gamma)(2t(1-\lambda)(\delta+P\gamma)+\Phi\lambda)\right)}{t\left(ft\gamma(4-3\lambda)^2-4\delta^2\Lambda-4P\gamma\Lambda(2\delta+P\gamma)\right)}, \tag{23}$$

the quantity for a single generic version is

$$q_{g(i)}^{PC} = \frac{(2-\lambda)\left(ft^2\gamma(4-3\lambda)+2\Phi(1-\lambda)(\delta+P\gamma)\right)}{t\Phi(4-3\lambda)+2\Psi(\delta+P\gamma)}. \tag{24}$$

The total generic quantity is equivalent to the generic market share

$$Q_g^{PC} = nq_{g(i)}^{PC} = \frac{\lambda(2-\lambda)\left(ft^2\gamma(4-3\lambda)+2\Phi(1-\lambda)(\delta+P\gamma)\right)}{t\left(ft\gamma(4-3\lambda)^2-4\Lambda(\delta+P\gamma)^2\right)}. \tag{25}$$

3.3 Reference Price

Consider now a reimbursement limit R, which is the maximum amount reimbursed irrespective of the drug price. Firms remain free to charge higher prices. If a patient wishes to purchase a drug, which is priced above the reference price, he/she has to pay the difference between the market price of the drug and the reference price in addition to the usual copayment

Assume that the reimbursement limit is binding for the brand-name drug, but not for the generic versions:

$$(1-\gamma)\, p_{g_i} \leq R \leq (1-\gamma)\, p_b. \tag{26}$$

Assume that for lower values of R, the generic versions are exempted from the reimbursement limit. This is, a generic version is available without an additional co-payment.

The marginal H-type is now given by

$$V - \delta - \gamma R - \left(p_b^{RL} - R\right) = V - t x_i^{H^{RL}} - \gamma p_{g(i)}^{RL}, \tag{27}$$

which yields

$$x_i^{H^{RL}} = \frac{\gamma R + \left(p_b^{RL} - R\right) - \gamma p_{g(i)}^{RL} + \delta}{t}. \tag{28}$$

The marginal L-type is not affected by the additional copayment.

Firms' profits are given as

$$\pi_b^{RL} = p_b^{RL}\,(1-\lambda)\left(1 - n2\frac{\gamma R + \left(p_b^{RL} - R\right) - \gamma p_{g(i)}^{RL} + \delta}{t}\right), \tag{29}$$

$$\pi_{g(i)}^{RL} = p_{g(i)}^{RL}\left((1-\lambda)\, 2\frac{\gamma R + \left(p_b^{RL} - R\right) - \gamma p_{g(i)}^{RL} + \delta}{t} + \lambda\frac{\frac{t}{n} + \gamma\left(p_{g(j)}^{RL} - p_{g(i)}^{RL}\right)}{t}\right) - f.$$

The number of firms is

$$n^{RL} = \frac{2\,(\lambda+1)\left(\Phi\,(3-2\lambda) - \Psi\left(R\,(1-\gamma) - \delta\right)\right)}{4\left(f t\gamma\,(3-2\lambda)^2 - \Lambda\left(R\,(1-\gamma) - \delta\right)^2\right)}. \tag{30}$$

First stage equilibrium drug prices are given as

$$p_b^{RL} = \frac{f\gamma t^2\,(3-2\lambda)\,(4-\lambda) + (2-\lambda)\left(R\,(1-\gamma) - \delta\right)\left(\Phi\,(\lambda+1) - 2t\,(1-\lambda)\left(R\,(1-\gamma) - \delta\right)\right)}{2\,(\lambda+1)\left(\Phi\,(3-2\lambda) - \Psi\left(R\,(1-\gamma) - \delta\right)\right)} \tag{31}$$

$$p_{g(i)}^{RL} = \frac{f\gamma t^2 (3-2\lambda) - \Phi (1-\lambda) (R(1-\gamma) - \delta)}{\gamma (\Phi (3-2\lambda) - \Psi (R(1-\gamma) - \delta))} \tag{32}$$

The equilibrium quantity for the brand-name drug is

$$q_b^{RL} = \frac{(1-\lambda) \left(f\gamma t^2 (4-\lambda)(3-2\lambda) + (2-\lambda) \left(\Phi (\lambda+1) (R(1-\gamma) - \delta) - 2t(1-\lambda) (R(1-\gamma) - \delta)^2 \right) \right)}{2t \left(ft\gamma (3-2\lambda)^2 - \Lambda (R(1-\gamma) - \delta)^2 \right)}, \tag{33}$$

the quantity for a single generic version is

$$q_{g(i)}^{RL} = \frac{(2-\lambda) \left(ft^2\gamma (3-2\lambda) - \Phi (1-\lambda) (R(1-\gamma) - \delta) \right)}{t (\Phi (3-2\lambda) - \Psi (R(1-\gamma) - \delta))}. \tag{34}$$

The total generic quantity is equivalent to the generic market share

$$Q_g^{RL} = nq_{g(i)}^{RL} = \frac{(\lambda+1)(2-\lambda) \left(ft^2\gamma (3-2\lambda) - \Phi (1-\lambda) (R(1-\gamma) - \delta) \right)}{2t \left(ft\gamma (3-2\lambda)^2 - \Lambda (R(1-\gamma) - \delta)^2 \right)}. \tag{35}$$

4 Regulation and Generic Competition

Both regulatory instruments, the price cap and the reimbursement limit, may affect generic competition in two ways. First, they may increase or reduce the total generic quantity, the generic market share. Second, they may have an effect on the number of generic competitiors. The importance of these two dimensions of generic competition differs with health policy objectives. For reducing public health expenditure, the generic market share is more important. For increasing consumer surplus, the generic market share may be more relevant for limiting copayments, but for reducing mismatch cost, the number of generic competitors is more important.

4.1 Generic Market Share

Both regulatory instruments decrease the generic market share:

$$Q_g - Q_g^{PC} > 0, Q_g - Q_g^{RL} > 0, \tag{36}$$

see Appendix for details. Under the price cap, the generic market share increases in the price cap P:

$$\frac{\partial Q_g^{PC}}{\partial P} > 0. \tag{37}$$

This is, relaxing regulation by increasing the limit for the price charged by the brand-name producer increases the generic market share. For a price cap equal to the unregulated brand-name price, i.e. no pricing restriction, the generic market share is maximized and corresponds to the generic market share under no regulation:

$$Q_g = Q_g^{PC}\left(P^{\max}\right). \tag{38}$$

Under the reimbursement limit, the generic market share decreases in the reimbursement limit:

$$\frac{\partial Q_g^{RL}}{\partial R} < 0. \tag{39}$$

Under the reimbursement limit, relaxing regulation by increasing the reimbursement limit decreases the generic market share, as it makes demand less elastic. Vice versa, a lower reimbursement limit corresponds to more elastic demand and increases the quantity sold by the generic competitors. For a reimbursement limit of zero, i.e. no reimbursement, the number of generic competitors is maximized and corresponds to the number of generic competitors under no regulation:

$$Q_g = Q_g^{RL}\left(R = 0\right). \tag{40}$$

4.2 Number of Generic Competitors

Both regulatory instruments decrease the generic market share:

$$n - n^{PC} > 0, n - n^{RL} > 0, \tag{41}$$

see Appendix for details. Under the price cap, a limit for the price charged by the brand-name producer also implies a lower generic price, since drug prices are strategic complements. As a lower price makes entry for the generic competitors less profitable, the number of generic competitors is lower under the price cap. Under the reimbursement limit, the introduction of a reimbursement limit decreases the number of generic competitors, even if the reimbursement limit is set to the unregulated brand-name price. This is because the reimbursement limit serves as a subsidy to the patients. For the

reimbursement limit is set to the unregulated brand-name price the brand-name producer has an incentive to lower the price. Consequently, as drug prices are strategic complements, a lower brand-name price corresponds to lower generic prices and a lower number of generic competitors, sinceentry is less profitable.

Under the price cap, the number of generic competitors increases in the price cap

$$\frac{\partial n^{PC}}{\partial P} > 0. \tag{42}$$

The price charged by the generic competitors increases in the price cap. Thus, a higher price cap makes entry for the generic competitors more profitable. For a price cap equal to the unregulated brand-name price, i.e. no pricing restriction, the number of generic competitors is maximized and corresponds to the number of generic competitors under no regulation:

$$n = n^{PC}\left(P^{\max}\right), \tag{43}$$

with $P^{\max} = p_b$.

Under the reimbursement limit, the number of generic competitors decreases in the reimbursement limit:

$$\frac{\partial n^{RL}}{\partial R} < 0.$$

A higher reimbursement limit makes demand less elastic, an increase of the reimbursement limit increases the brand-name drug price by more than the generic price, making entry less profitable. For a reimbursement limit of zero, i.e. no reimbursement, the number of generic competitors is maximized and corresponds to the number of generic competitors under no regulation:

$$n = n^{RL}\left(R = 0\right). \tag{44}$$

Given that under the price cap, the number of generic competitors is maximized for $P^{\max} = p_b$ and decreases with a reduction in the price cap and under the reimbursement limit, the number of generic competitors is maximized for $R = 0$ and decreases with an increase in the reimbursement limit, there is an amount B, for which the number of generic competitors is the same under both instruments.

$$n^{PC}\left(B^*\right) = n^{RL}\left(B^*\right),$$

see Appendix for details. This implies, irrespective of whether B is set as a price cap or a reimbursement limit, the number of generic competitors is the same. For amounts higher

than B, the number of generic competitors is higher under a price cap, for amounts lower than B, the number of generic competitors is higher under a reimbursement limit.

5 Conclusion

In this paper, I have studied the impact of a price cap and a reimbursement limit on generic competition. Both regulatory instruments reduce the generic market share as well as the number of generic competitors. Under the price cap, the generic market share and the number of generic competitors are maximized for a price cap equal to the unregulated brand-name price, i.e. no pricing restriction, and decrease with a reduction of the price cap. Under the reimbursement limit, the generic market share and the number of generic competitors are maximized for a reimbursement of zero, i.e. no reimbursement, and decrease with an increase of the reimbursement limit.

Thus, whether a price cap or a reimbursement limit is preferable in terms of reducing generic competition less depends on the degree of regulation, i.e. the amount limiting prices or reimbursement. For rather soft regulation with little restriction on prices or reimbursement, the generic market share and the number of generic competitors are higher under a price cap. For rather strict regulation with extensive restriction on prices or reimbursement, the generic market share and the number of generic competitors are higher under a reimbursement limit.

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6 Appendix

For $p_b = \frac{t(4-\lambda)-2n\delta(2-\lambda)}{4n\gamma(3-2\lambda)} \geq 0$, $n \leq \frac{t(4-\lambda)}{2\delta(2-\lambda)}$.

As $n = \frac{2(\lambda+1)\left(\sqrt{ft^3\gamma(2-\lambda)}(3-2\lambda)+\Psi\delta\right)}{4\left(ft\gamma(3-2\lambda)^2-\Lambda\delta^2\right)}$, $n \leq \frac{t(4-\lambda)}{2\delta(2-\lambda)}$ is equivalent to $f \geq \frac{4\delta^2(2-\lambda)}{t\gamma(4-\lambda)^2}$.

For $n^{RL} \geq 0$, $\Phi(3-2\lambda) - \Psi(R(1-\gamma)-\delta) \geq 0$

$\wedge ft\gamma(3-2\lambda)^2 - \Lambda(R(1-\gamma)-\delta)^2 \geq 0$

or $\Phi(3-2\lambda) - \Psi(R(1-\gamma)-\delta) \leq 0$

$\wedge ft\gamma(3-2\lambda)^2 - \Lambda(R(1-\gamma)-\delta)^2 \leq 0$.

If $R \leq \sqrt{\frac{ft\gamma(3-2\lambda)^2}{\Lambda(1-\gamma)^2}}$, $\Phi(3-2\lambda) - \Psi(R(1-\gamma)-\delta) \geq 0$

$\wedge ft\gamma(3-2\lambda)^2 - \Lambda(R(1-\gamma)-\delta)^2 \geq 0$

and $n^{RL} \geq 0$.

If $R \geq \sqrt{\frac{ft\gamma(3-2\lambda)^2}{\Lambda(1-\gamma)^2}}$, $\Phi(3-2\lambda) - \Psi(R(1-\gamma)-\delta) \leq 0$

$\wedge ft\gamma(3-2\lambda)^2 - \Lambda(R(1-\gamma)-\delta)^2 \leq 0$

and $n^{RL} \geq 0$

$Q_g - Q_g^{PC}$

$= \frac{1}{2}(\lambda+1)(2-\lambda)\frac{ft^2\gamma(3-2\lambda)+\Phi\delta(1-\lambda)}{t\left(ft\gamma(3-2\lambda)^2-\delta^2\Lambda\right)}$

$-\lambda(2-\lambda)\frac{ft^2\gamma(4-3\lambda)+2\Phi(1-\lambda)(\delta+P\gamma)}{t\left(ft\gamma(4-3\lambda)^2-4\Lambda(\delta+P\gamma)^2\right)} > 0$

since $\frac{d\left(Q_g-Q_g^{PC}\right)}{dP} =$

$-\frac{2\lambda\gamma(2-\lambda)(1-\lambda)\left(4P\gamma(2-\lambda)(1-\lambda)\left(\Phi(1-\lambda)(2\delta+P\gamma)+ft^2\gamma(4-3\lambda)\right)+4\Phi\delta^2\Lambda+ft\gamma(4-3\lambda)(\Phi(4-3\lambda)+4\delta\Psi)\right)}{t\left(ft\gamma(4-3\lambda)^2-4\delta^2\Lambda-4P\gamma\Lambda(2\delta+P\gamma)\right)^2}$

and $Q_g^{PC}(P^{\max}) = Q_g$

with $P^{\max} = \frac{ft^2\gamma(3-2\lambda)(4-\lambda)-2t\delta^2(1-\lambda)(2-\lambda)-\Phi\delta(\lambda+1)(2-\lambda)}{2\gamma(1+\lambda)(\Phi(3-2\lambda)+\delta\Psi)} = p_b$.

$\frac{\partial Q_g^{PC}}{\partial P} = 2\lambda\gamma(1-\lambda)(2-\lambda)\frac{4P\gamma(1-\lambda)(2-\lambda)\left(\Phi(1-\lambda)(2\delta+P\gamma)+ft^2\gamma(4-3\lambda)\right)+ft\gamma(4-3\lambda)(\Phi(4-3\lambda)+4\delta\Psi)}{t\left(ft\gamma(4-3\lambda)^2-4\Lambda(\delta+P\gamma)^2\right)^2}$

$+2\lambda\gamma(1-\lambda)(2-\lambda)\frac{4\Phi\delta^2\Lambda}{t\left(ft\gamma(4-3\lambda)^2-4\Lambda(\delta+P\gamma)^2\right)^2} > 0$.

$Q_g - Q_g^{RL}$

$= \frac{1}{2}(\lambda+1)(2-\lambda)\frac{ft^2\gamma(3-2\lambda)+\Phi\delta(1-\lambda)}{t\left(ft\gamma(3-2\lambda)^2-\delta^2\Lambda\right)}$

$-\frac{1}{2t}(\lambda+1)(2-\lambda)\frac{ft^2\gamma(3-2\lambda)-\Phi(1-\lambda)(R(1-\gamma)-\delta)}{ft\gamma(3-2\lambda)^2-R\Lambda(1-\gamma)(R(1-\gamma)-2\delta)-\delta^2\Lambda} > 0$,

if $ft\gamma(3-2\lambda)(\Phi(3-2\lambda)+2\delta\Psi)+\Phi\delta^2\Lambda$

$> R(1-\lambda)(2-\lambda)(1-\gamma)\left(\Phi\delta(1-\lambda)+ft^2\gamma(3-2\lambda)\right)$

$\Leftrightarrow R < \widehat{R} = \frac{ft\gamma(3-2\lambda)(\Phi(3-2\lambda)+2\delta\Psi)+\Phi\delta^2\Lambda}{(1-\lambda)(2-\lambda)(1-\gamma)(\Phi\delta(1-\lambda)+ft^2\gamma(3-2\lambda))}$

$= \frac{\delta(1-\lambda)(2-\lambda)+(3-2\lambda)\sqrt{ft\gamma(2-\lambda)}}{(1-\gamma)(1-\lambda)(2-\lambda)}$,

since $\Phi = \sqrt{ft^3\gamma(2-\lambda)}$.

$\widehat{R} > R^{\max} = \frac{ft^2\gamma(3-2\lambda)(4-\lambda)-2\delta^2\Psi-\Phi\delta(\lambda+1)(2-\lambda)}{2\gamma(1+\lambda)(\Phi(3-2\lambda)+\delta\Psi)} = p_b$
$\vee \widehat{R} < R^{\max}$. $Q_g = Q_g^{RL}\,(R=0)$
$\frac{\partial Q_g^{RL}}{\partial R} = -(1-\gamma)(1-\lambda)(2-\lambda)(\lambda+1)\frac{ft\gamma(3-2\lambda)(\Phi(3-2\lambda)+2\delta\Psi)+\Phi\delta^2\Lambda}{2t\left(ft\gamma(3-2\lambda)^2-R\Lambda(1-\gamma)(R(1-\gamma)-2\delta)-\delta^2\Lambda\right)^2}$
$+(1-\gamma)(1-\lambda)(2-\lambda)(\lambda+1)\frac{R(2-\lambda)(1-\lambda)(1-\gamma)\left(2ft^2\gamma(3-2\lambda)-\Phi(1-\lambda)(R(1-\gamma)-2\delta)\right)}{2t\left(ft\gamma(3-2\lambda)^2-R\Lambda(1-\gamma)(R(1-\gamma)-2\delta)-\delta^2\Lambda\right)^2} < 0$
if $R < \widehat{R}$.
$n - n^{PC} = \frac{ft\Phi\gamma(1-\lambda)(4-\lambda)(3-2\lambda)(4-3\lambda)+ft\Psi\gamma\delta\left(16-44\lambda+33\lambda^2-7\lambda^3\right)-2\Lambda\Phi\delta^2\left(6-2\lambda-\lambda^2\right)}{2\left(ft\gamma(3-2\lambda)^2-\Lambda\delta^2\right)\left(ft\gamma(4-3\lambda)^2-4\Lambda(P\gamma+\delta)^2\right)}$
$-\frac{4P\Lambda\Phi\gamma(\lambda+1)(3-2\lambda)(2\delta+P\gamma)+4\Psi\Lambda\delta(\delta+P\gamma)(\delta+P\gamma+P\lambda\gamma)+4Pft\Psi\lambda\gamma^2(3-2\lambda)^2}{2\left(ft\gamma(3-2\lambda)^2-\Lambda\delta^2\right)\left(ft\gamma(4-3\lambda)^2-4\Lambda(P\gamma+\delta)^2\right)} > 0$
with $\Lambda = (2-\lambda)(1-\lambda)^2$, and $\Psi = t(1-\lambda)(2-\lambda)$,
since $n = n^{PC}\,(P^{\max}) = 0$
with $P^{\max} = \frac{ft^2\gamma(3-2\lambda)(4-\lambda)-2\delta^2\Psi-\Phi\delta(\lambda+1)(2-\lambda)}{2\gamma(1+\lambda)(\Phi(3-2\lambda)+\delta\Psi)} = p_b$
and $\frac{\partial n^{PC}}{\partial P}$
$= 2\lambda\gamma(1-\lambda)(2-\lambda)\frac{ft^2\gamma(4-3\lambda)^2+4(1-\lambda)(\delta+P\gamma)(\Phi(4-3\lambda)+\Psi(\delta+P\gamma))}{\left(ft\gamma(4-3\lambda)^2-4\Lambda(P\gamma+\delta)^2\right)^2} > 0.$
$n - n^{RL}$
$= \frac{R(1-\gamma)(1-\lambda)(2-\lambda)(1+\lambda)\left(ft^2\gamma(3-2\lambda)^2+(1-\lambda)\left(2\Phi\delta(3-2\lambda)+\delta^2\Psi\right)\right)}{2\left(ft\gamma(3-2\lambda)^2-\Lambda\delta^2\right)\left(ft\gamma(3-2\lambda)^2-\Lambda(R(1-\gamma)-\delta)^2\right)}$
$-\frac{R(1-\gamma)\Lambda(1+\lambda)(R(1-\gamma)(\Phi(3-2\lambda)+\delta\Psi))}{2\left(ft\gamma(3-2\lambda)^2-\Lambda\delta^2\right)\left(ft\gamma(3-2\lambda)^2-\Lambda(R(1-\gamma)-\delta)^2\right)} > 0,$
since $n = n^{RL}\,(R=0)$ and
$\frac{\partial n^{RL}}{\partial R} = -\frac{(1-\gamma)(1-\lambda)(2-\lambda)(\lambda+1)(R(1-\gamma)(1-\lambda)(R\Psi(1-\gamma)+2t\lambda\delta(3-\lambda)-2(\Phi(3-2\lambda)+2t\delta)))}{2\left(R\Lambda(\gamma-1)(-R+2\delta+R\gamma)+\delta^2\Lambda+ft\gamma(2\lambda-3)^2\right)^2}$
$-\frac{(1-\gamma)(1-\lambda)(2-\lambda)(\lambda+1)\left(ft^2\gamma(3-2\lambda)^2+\delta^2(1-\lambda)\Psi+2\Phi\delta(1-\lambda)(3-2\lambda)\right)}{2\left(R\Lambda(\gamma-1)(-R+2\delta+R\gamma)+\delta^2\Lambda+ft\gamma(2\lambda-3)^2\right)^2} < 0$
if $R < \widehat{R} = \frac{\delta(1-\lambda)(2-\lambda)+(3-2\lambda)\sqrt{ft\gamma(2-\lambda)}}{(1-\gamma)(1-\lambda)(2-\lambda)} < 0.$
$n - n^{RL}\,(R^{\max}) = \frac{(\lambda+1)(1-\gamma)(\Phi(3-2\lambda)+\Psi\delta)\Delta_1\Delta_2}{2\Delta_3\Delta_4}$
with $\Lambda = (2-\lambda)(1-\lambda)^2$, $\Psi = t(1-\lambda)(2-\lambda)$,
$R^{\max} = \frac{ft^2\gamma(3-2\lambda)(4-\lambda)-2\delta^2\Psi-\Phi\delta(\lambda+1)(2-\lambda)}{2\gamma(1+\lambda)(\Phi(3-2\lambda)+t\delta(1-\lambda)(2-\lambda))} = p_b,$
$\Delta_1 = ft^2\gamma(4-\lambda)(3-2\lambda)^2-\Phi\delta(2-\lambda)(3-2\lambda)(\lambda+1)-\Psi\delta^2(\lambda+1)(2-\lambda)-t\Lambda\delta^2(4-\lambda),$
$\Delta_2 = \Psi\Lambda\delta^2(\lambda+1)(2-\lambda+4\gamma-3\lambda\gamma)+t\Lambda^2\delta^2(1-\gamma)(4-\lambda)+\Lambda\Phi\delta(\lambda+1)(3-2\lambda)(2-\lambda+10\gamma-7\lambda\gamma)$
$+ft\gamma(2\lambda-3)^2(2\Psi\gamma(\lambda+1)(3-2\lambda)-t\Lambda(4-\lambda)(1-\gamma)),$
$\Delta_3 = ft\gamma(2\lambda-3)^2-\Lambda\delta^2,$
$\Delta_4 = 4ft\gamma^3(\lambda+1)^2(3-2\lambda)^4(\Phi(3-2\lambda)+\Psi\delta)^2-t^2\Lambda(1-\gamma)^2(4-\lambda)^2\left(ft\gamma(3-2\lambda)^2-\Lambda\delta^2\right)^2$
$+2t\Lambda\delta(\lambda+1)(4-\lambda)(1-\gamma)(2-\lambda+4\gamma-3\lambda\gamma)\Phi(3-2\lambda)+\Psi\delta\left(ft\gamma(3-2\lambda)^2-\Lambda\delta^2\right)$
$-\Lambda\delta^2(1+\lambda)^2(2-\lambda+4\gamma-3\lambda\gamma)^2(\Phi(3-2\lambda)+\Psi\delta)^2.$
$\Delta_1 > 0,$
since for $f = f^{\min} = \frac{4\delta^2(2-\lambda)}{t\gamma(4-\lambda)^2}$

$\Delta_1 = 0$ and $\frac{\partial \Delta_1}{\partial f} \geq 0$
if $f \geq f^* = \frac{\delta^2(\lambda+1)^2(2-\lambda)^3}{4t\gamma(4-\lambda)^2(3-2\lambda)^2}$, $f^* < f^{\min}$.
$\Delta_2 > 0$
if $f < \widetilde{f} = \frac{-b+\sqrt{-4ac+b^2}}{2a}$,
with $a = t^2\gamma^2 (2\lambda-3)^4 (t\Lambda (1-\gamma)(4-\lambda) - 2\Psi\gamma(\lambda+1)(3-2\lambda))^2$
$b = t\Lambda\gamma\delta^2 (2\lambda-3)^2 \left(t^2\Lambda(\lambda+1)^2(\lambda-2)(\lambda-10\gamma+7\lambda\gamma-2)^2\right)$
$-t\Lambda\gamma\delta^2(2\lambda-3)^2(2(t\Lambda(1-\gamma)(4-\lambda)-2\Psi\gamma(\lambda+1)(3-2\lambda))(t\Lambda(1-\gamma)(4-\lambda)))$
$-t\Lambda\gamma\delta^2(2\lambda-3)^2(2(t\Lambda(1-\gamma)(4-\lambda)-2\Psi\gamma(\lambda+1)(3-2\lambda))(\Psi(\lambda+1)(4\gamma-\lambda-3\lambda\gamma+2)))$,
$c = \Lambda^2\delta^4 (t\Lambda(1-\gamma)(4-\lambda) + \Psi(\lambda+1)(4\gamma-\lambda-3\lambda\gamma+2))^2$.
$\Delta_3 > 0$,
since for $f = f^{\min} = \frac{4\delta^2(2-\lambda)}{t\gamma(4-\lambda)^2}$ $\Delta_3 > 0$
and $\frac{\partial \Delta_3}{\partial f} > 0$.
$\Delta_4 > 0$ if $f < \widetilde{f}$.
For $f < \widetilde{f}$ $\Delta_2 > 0 \wedge \Delta_4 > 0$,
for $f > \widetilde{f}$ $\Delta_2 < 0 \wedge \Delta_4 < 0$,
so $\frac{(\lambda+1)(1-\gamma)(\Phi(3-2\lambda)+\Psi\delta)\Delta_1\Delta_2}{2\Delta_3\Delta_4} > 0$ for $f \in [f^{\min}, \infty]$.
$n^{PC}(B) = n^{RL}(B)$
$\Leftrightarrow \frac{\lambda(\Phi(4-3\lambda)+2\Psi(B\gamma+\delta))}{ft\gamma(4-3\lambda)^2-4\Lambda(B\gamma+\delta)^2} = \frac{2(\lambda+1)(\Phi(3-2\lambda)-\Psi(B(1-\gamma)-\delta))}{4\left(ft\gamma(3-2\lambda)^2-\Lambda(B(1-\gamma)-\delta)^2\right)}$
$\Leftrightarrow B^3 + B^2 \frac{2\Psi\delta\left(-\lambda-2\gamma+3\gamma^2+2\lambda\gamma\right)-\Phi\left(4\lambda-3\lambda^2-6\gamma^2+\lambda^2\gamma^2-8\lambda\gamma+2\lambda\gamma^2+6\lambda^2\gamma\right)}{2\Psi\gamma(\gamma-1)(\lambda+\gamma)}$
$+B\frac{4\Psi\Lambda\delta^2(\lambda+3\gamma-1)-4\Lambda\Phi\delta\left(-4\lambda-6\gamma+3\lambda^2+2\lambda\gamma+\lambda^2\gamma\right)+ft\Psi\gamma\left(-8\lambda-16\gamma-15\lambda^2+9\lambda^3+44\lambda\gamma-33\lambda^2\gamma+7\lambda^3\gamma+16\right)}{4\Psi\Lambda\gamma(\gamma-1)(\lambda+\gamma)}$
$+\frac{4\Psi\Lambda\delta^3-2\Lambda\Phi\delta^2\left(2\lambda+\lambda^2-6\right)+ft\gamma\left(-48\Phi-16\Psi\delta+128\Phi\lambda-121\Phi\lambda^2+47\Phi\lambda^3-6\Phi\lambda^4-33\Psi\lambda^2\delta+7\Psi\lambda^3\delta+44\Psi\lambda\delta\right)}{4\Psi\Lambda\gamma(\gamma-1)(\lambda+\gamma)}$

$= 0$,
$\Leftrightarrow B = -\sqrt{-\frac{4}{3}\left(\beta-\frac{\alpha^2}{3}\right)}\cos\left(\frac{1}{3}\arccos\left(-\frac{\left(\frac{2\alpha^3}{27}-\frac{\alpha\beta}{3}+\eta\right)}{2}\sqrt{-\frac{27}{\left(\beta-\frac{\alpha^2}{3}\right)^3}}\right)+\frac{\pi}{3}\right)-\frac{\alpha}{3}$,
with $\alpha = \frac{2\Psi\delta\left(\lambda+2\gamma-3\gamma^2-2\lambda\gamma\right)+\Phi\left(4\lambda-3\lambda^2-6\gamma^2+\lambda^2\gamma^2-8\lambda\gamma+2\lambda\gamma^2+6\lambda^2\gamma\right)}{2\Psi\gamma(1-\gamma)(\lambda+\gamma)}$,
$\beta = \frac{4\Psi\Lambda\delta^2(1-\lambda-3\gamma)-4\Lambda\Phi\delta\left(4\lambda+6\gamma-3\lambda^2-2\lambda\gamma-\lambda^2\gamma\right)-ft\Psi\gamma\left(16-8\lambda-16\gamma-15\lambda^2+9\lambda^3+44\lambda\gamma-33\lambda^2\gamma+7\lambda^3\gamma\right)}{4\Psi\Lambda\gamma(1-\gamma)(\lambda+\gamma)}$,
$\eta = \frac{ft\gamma\left(\Phi(1-\lambda)(4-\lambda)(3-2\lambda)(4-3\lambda)+\Psi\delta\left(-7\lambda^3+33\lambda^2-44\lambda+16\right)\right)-4\Psi\Lambda\delta^3-2\Lambda\Phi\delta^2\left(6-2\lambda-\lambda^2\right)}{4\Psi\Lambda\gamma(1-\gamma)(\lambda+\gamma)}$.