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**PHARMACEUTICAL REGULATION AND
HEALTH POLICY OBJECTIVES**

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Pharmaceutical Regulation and Health Policy Objectives

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Abstract

This paper analyzes a maximum price system and a reference price system in a vertical differentiation model with a brand-name drug and a generic. In particular, both instruments are compared with respect to their performance in reducing public expenditure, limiting financial exposure of patients, improving access to pharmaceuticals, and stimulating competition. For identical regulatory prices, free pricing under the reference system tends to result in a higher price for the brand-name drug. For identical price reductions of the brand-name drug, the lower reimbursement amount under the reference price system results in lower health expenditure, but higher financial exposure of patients. Total welfare is higher under the maximum price system.

JEL Classification: I18, L50, H51

Keywords: pharmaceutical regulation, reference price, maximum price, price cap, health policy objectives

1 Introduction

This paper compares a maximum price system and a reference price system with respect to their performance in reducing public expenditure, limiting financial exposure of patients, improving access to pharmaceuticals, and stimulating competition.

This analysis is motivated by the following observations: The two regulatory instruments – the maximum price system and the reference price system – examined in this paper are applied in almost all Western European countries. Pharmaceutical markets are characterized by patients not paying the full price of pharmaceuticals out-of-pocket, but only a co-payment, while the health insurance reimburses the remaining part. In a system of public insurance, reimbursement brings about public expenditure. An increase of co-payments would relieve the public purse, but contradict distributive objectives in the supply of pharmaceuticals. Consequently, regulatory

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instruments such as the maximum price system or the reference price system are introduced to reduce public health expenditure. But at the same time, government interventions may induce a conflict between expenditure reduction and distributive objectives, such as limiting financial exposure of patients and improving access to pharmaceuticals.

The main form of supply-side regulation is direct price control, in which the regulatory body sets a price cap that can be charged for a drug. In the European Union, all countries except for Denmark, Germany, the Netherlands, Malta, Sweden, and the UK control pharmaceutical prices directly (Espin & Rovira, 2007).

A common form of demand side or reimbursement regulation is the reference price system, in which the reference price is the maximum reimbursement for a group of drugs. The group of pharmaceuticals is defined in terms of interchangeability, 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 (López-Casasnovas & Puig-Junoy, 2000). Firms remain free to charge higher prices. If the manufacturer's price exceeds the reference price, the patient has to pay the difference between the market price and the reference price him/herself (Danzon, 2001). That is, the reference price system involves an additional co-payment, 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 co-payment (López-Casasnovas & Puig-Junoy, 2000). In Western Europe, Belgium, Denmark, Estonia, Germany, Greece, Hungary, Italy, the Netherlands, Poland, Portugal, and Spain¹ use reference price systems (Espin & Rovira, 2007).

Besides potential differences in performance with respect to health policy objectives, the choice between both regulatory instruments is determined by different economic rationales. Supply side measures are commonly thought to limit the market power of pharmaceutical firms stemming from patients' and physicians' price insensitivity (Scherer, 1996). Reference pricing aims at increasing market transparency and allowing consumers to compare a drug's price in relation to prices of suitable substitutes (Danzon, 2001; López-Casasnovas & Puig-Junoy, 2000). Thereby reference pricing introduces an element of price-sensitivity and producers may only maintain prices above the reference price, if additional quality or value is associated with the respective drug (Espin & Rovira, 2007). By making demand more price elastic, reference pricing creates incentives to substitute less expensive generics for higher priced brand-name drugs.

The main objective of pharmaceutical regulation has been the reduction of public expenditure. An aging population with growing health needs, technological progress, and pharmaceutical market imperfections result in high expenditure for pharmaceuticals. Public insurance schemes bear the majority of these expenses (Danzon, 1997). Pharmaceutical markets are characterized by agency imperfections, informational asymmetries and moral hazard, that create reduced price sensitivity on the demand side and a certain degree of market power on the supply side (Mossialos

¹Some states, e.g. Finland, apply both the maximum price and the reference price system. In Finland, price control applies to wholesale prices, which are calculated on basis of wholesale prices in several other European countries (Espin & Rovira, 2007). Reference pricing then limits reimbursement of the retail price. That is, in this case, both instruments are applied at different levels, the maximum price system at the wholesale level and reference pricing at the retail level.

& Le Grand, 1999; Hurley, 2001).

In an effort to reduce moral hazard in health care utilization by making patients more aware of the prices of pharmaceuticals or health care services and reducing the use of pharmaceuticals or services that are not really necessary, co-payments have been introduced in basically all Western European countries, mostly in the form of coinsurance rates, where patients pay a percentage of the price (Mossialos & Le Grand, 1999, Robinson, 2002). In the European Union, various forms of coinsurance (with coinsurance rates fixed or depending on drug classes or price levels) are applied in Belgium, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Latvia, Lithuania, Poland, Portugal, Slovakia, Slovenia, Spain, and Sweden (Espin & Rovira, 2007)². Evidence from the RAND Health Experiment suggests that utilization of pharmaceuticals or health care services is more responsive to co-payments for low-income groups (see Zweifel & Breyer, 2006 for a survey). Price elasticity of demand increases with the coinsurance rate, but as guaranteeing broad access to services is a policy objective, the coinsurance rate cannot constitute an instrument of cost containment. Several EU member states such as Belgium, Finland, France, Germany, and the Netherlands have introduced a ceiling for all co-payments (Mossialos & Le Grand, 1999). Also, empirically, co-payments have never been a preferred instrument of cost containment, nor has the extent, that is the percentage of the price to be paid by patients, increased significantly (Mossialos & Le Grand, 1999). The model used in this paper features coinsurance rates, whereby co-payments result in out-of-pocket expenditure for patients and reimbursement in publicly funded health expenditure. This allows me to analyze also the effect of regulation on public pharmaceutical expenditure and financial exposure of patients.

Competition between off-patent brand-name drugs and generics is mainly characterized by first-mover advantages and consumer perception. Generics tend to enter the market at substantial discounts to the price prevailing before patent expiry of the brand-name drug (Scherer, 2001). Additional generic competitors then result in further price reductions, whereas the price of the brand-name drug remains stable or even increases (Scherer, 2001). The observation of increasing brand-name prices in response to generic entry has been labelled the generic competition paradox. Frank & Salkever (1992) explain the diverging price trends of brand-name drugs and generics with a segmented demand side of price-sensitive consumers willing to switch to generic and brand-loyal consumers willing to pay a higher price for the brand-name drug. The existence of a brand-loyal segment implies that brand-name drugs and generics are not considered to be homogenous products by consumers, but rather differentiated products. In addition to objective differences between brand-name drugs with respect to additives, consumers sometimes associate a lower quality with generic versions (see Gaither et al., 2001 for a survey of consumers' perception of generics). Also, the inability to assess the quality of drugs before consumption and the risk of bad choices such as adverse side effects contributes to first-mover advantages for brand-name producers, allowing them to maintain market shares at substantial higher prices (Scherer,

²Of the remaining countries, the Netherlands and Malta have no co-payment, Austria, Italy, and the UK apply a flat rate (with a charge per service), and Ireland and Sweden apply a deductible (consumers have to pay the first x Euros, until insurance coverage begins) (Espin & Rovira, 2007).

1996). The model in this paper therefore explicitly assumes a heterogeneous demand side, where consumers differ in their valuation of the drug, and a certain degree of product differentiation between the brand-name drug and the generic versions - either due to consumer perceptions or firms' investment decisions.

The paper most closely related to this paper is Brekke, Holmas & Straume (2010), who compare price cap regulation with reference pricing. Their model suggests that reference pricing results in price reductions, which are higher for brand-name drugs, and correspondingly it induces stronger generic competition and lower brand-name market shares (Brekke, Holmas & Straume, 2010). This is in line with empirical evidence from Pavcnik (2002), who studies prices for oral antidiabetics and antiulcers in Germany between 1986 and 1996. She finds major price reductions for both brand-name and generic drugs, with larger reductions for brand-name prices. 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).

Whereas the existing literature mainly analyzes firms' pricing behavior and the potential of reference pricing in reducing drug prices, this analysis takes a broader perspective and focuses more on the overall implications of these regulatory instruments in more than one dimension. In other words, as pharmaceutical regulation may exhibit a trend of inhibiting competition due to less generic entry, not only price reductions but also high generic market shares and a sufficient degree of competition are essential (Danzon, Wang & Wang, 2005). Moreover, price reductions may not be politically intended if they result in higher financial exposure of patients. Consequently, the purpose of this paper is to analyze the performance of price caps and reference pricing with respect to several policy objectives. Furthermore, the explicit comparison of both instruments takes into account that both instruments constitute policy alternatives and that the relative importance of health policy objectives determines which instrument is chosen. The vertical product differentiation with a heterogenous demand side takes into account that both objective and subjective differences between brand-name drugs and generics exist and that consumers choose which version to buy based on their valuation of the drug. The result is an endogenous segmentation of the demand side, with a segment of consumers with high valuation of pharmaceuticals buying the brand-name drug and a segment of consumers with an intermediate valuation purchasing the generic. Consumers with a very low valuation will buy neither version of the drug. This allows me to analyze the effect of regulation on the access to pharmaceuticals, if it results in a change of market coverage. The maximum price system is modelled as a price cap amounting to the generic price in the benchmark case of no regulation plus a mark-up, the reference price system assumes a reference price as the weighted average of brand-name and generic price. Both constructions allow me to analyze different degrees of regulation explicitly.

For identical regulatory degrees, the endogenous specification of the reference price system

captures the firms' strategic response to the introduction of a reimbursement limit and generates higher price reductions for the brand-name drug under the reference price system. For identical regulatory prices, the reference price system tends to result in higher drug prices, as free pricing associated with the reference price system enables the brand-name producer to skim off additional willingness to pay by setting a price above the reference price. The additional co-payment element (patients have to pay the difference between the market price of the brand-name drug and the reference price) results in higher financial exposure of patients, but also lower public expenditure. Total welfare is higher under the maximum price system.

The rest of the paper is organized as follows. The next section presents the vertical differentiation model with a brand-name drug producer and a generic drug producer. Section 3 analyzes the benchmark case of no pharmaceutical regulation, the case of regulation through a price cap (maximum price system), and the case of regulation through a reimbursement limit (reference price system). Section 4 compares the regulatory scenarios with respect to the health policy objectives of the reduction of public expenditure, the limitation of financial exposure of patients, the improvement of access to pharmaceuticals, and the stimulation of competition. Section 5 analyzes welfare and section 6 concludes.

2 The Model

Consider a therapeutic market with two competing drugs, an off-patent brand-name drug b and the corresponding generic version g . This corresponds to the duopolistic transition period after patent expiry, with the first generic having already entered the market.

Both drugs contain the same active ingredient, but differ in both objective and subjective terms. On the one hand, generics and brand-name drugs show considerable differences with respect to binders, fillers, preservatives and density of packing (bioequivalence³), which may affect therapeutic efficacy (Scherer, 1996). On the other hand, generics may be perceived as of lower quality (see Gaither et al. (2001) for a survey on the lower quality perception of generics). In addition, there is evidence that the price of a drug may serve as quality indicator (Waber et al., 2008). Also uncertainty with respect to whether the generic version is really equivalent to the brand-name version may contribute to a lower willingness to pay for the generic. 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).

Consumers differ with respect to their gross valuation of drug consumption θ , which is uniformly distributed on the interval normalized to unity. A consumer with a positive net utility of drug consumption will choose the most preferred drug version by trading off (objective and perceived) drug quality against drug co-payment. The higher the gross valuation of drug treatment θ , the more the consumer is willing to pay in order to purchase the (high-quality) brand-name

³Differences in bioequivalence may imply also differences in bioavailability, which refers to the rate and extent, at which the active ingredient is absorbed.

drug. The consumer heterogeneity can be interpreted as differences in willingness to pay for a brand-name, differences in risk aversion regarding the trial of substitutes, differences in the severity of the condition or the level of suffering or differences in prescription practices (see e.g. Brekke, Holmas & Straume, 2010). This results in an endogenous segmentation of the demand side.

A consumer who buys a drug i obtains a net utility of

$$U(\theta, \tau, c_i) = \begin{cases} \theta - c_i & \text{if } i = b \\ \theta\tau - c_i & \text{if } i = g, \end{cases} \quad (1)$$

where the parameter τ captures subjective and/or objective differences⁴ between the brand-name drug and the generic version and c_i is the patient co-payment for drug i . The utility derived from no drug purchase is zero.

The marginal consumer who is indifferent between buying the brand-name drug b or the generic version g has a gross valuation θ^* , given by

$$\theta^* - c_b = \theta^*\tau - c_g, \text{ yielding } \theta^* = \frac{c_b - c_g}{1 - \tau}$$

while a consumer who is indifferent between buying the generic and not buying at all has a gross valuation $\underline{\theta}$, given by

$$\underline{\theta}\tau - c_g = 0, \text{ yielding } \underline{\theta} = \frac{c_g}{\tau}.$$

Hence, demand for brand-name drug b and for the generic g is given by

$$q_b = 1 - \frac{c_g}{\tau} \text{ and } q_g = \frac{c_g}{\tau} - \frac{c_g}{\tau}.$$

Production technologies exhibit constant marginal costs, which are normalized to zero for simplicity, such that profits are given as

$$\Pi_i = p_i q_i. \quad (2)$$

3 Regulatory Scenarios

3.1 No Regulation

Consider a system with no regulation as a benchmark. Consumers are partially insured, a co-payment in the form of a proportion of the price (coinsurance) applies. The remaining amount is reimbursed by the health insurance.

⁴The quality difference between the brand-name and the generic version may be considered as either an exogenous difference stemming from the different perception of brand-name drugs and generics or as an endogenous one emerging from the pharmaceutical firms' investment decision. Both are equivalent with respect to mechanics of the model.

Co-payment for the brand-name drug and the generic is given as

$$c_i = \kappa p_i, \quad (3)$$

where κ is the coinsurance rate.

Thus, demand functions are given as

$$q_b = 1 - \frac{\kappa(p_b - p_g)}{\tau} \text{ and } q_g = \frac{\kappa(p_b - p_g)}{\tau} - \frac{\kappa p_g}{1 - \tau}. \quad (4)$$

The firms' profits are given as

$$\Pi_b = p_b \left(1 - \frac{\kappa(p_b - p_g)}{\tau} \right) \text{ and } \Pi_g = p_g \left(\frac{\kappa(p_b - p_g)}{\tau} - \frac{\kappa p_g}{1 - \tau} \right). \quad (5)$$

Equilibrium prices are

$$p_b = \frac{2\tau}{\kappa(3 + \tau)} \text{ and } p_g = \frac{\tau(1 - \tau)}{\kappa(3 + \tau)}. \quad (6)$$

and equilibrium quantities are

$$q_b = \frac{2}{3 + \tau} \text{ and } q_g = \frac{1}{3 + \tau}. \quad (7)$$

Profits are given by

$$\Pi_b = \frac{4\tau}{\kappa(3 + \tau)^2} \text{ and } \Pi_g = \frac{\tau(1 - \tau)}{\kappa(3 + \tau)^2}. \quad (8)$$

3.2 Maximum Price System

Consider a maximum price system. The regulator sets a maximum price equal to the price of the generic plus a markup. Health policy makers often compare prices for brand-name drugs and generics, as both versions of the drug are considered to be equivalent.

A maximum price of

$$\hat{p} = \underbrace{\frac{\tau(1 - \tau)}{\kappa(3 + \tau)}}_{p_g} + (1 - m) \underbrace{\frac{\tau(1 + \tau)}{\kappa(3 + \tau)}}_{\mu = p_b - p_g}, \quad (9)$$

corresponds to the generic price in the no regulation case ($p_g = \frac{\tau(1 - \tau)}{\kappa(3 + \tau)}$) plus a fraction $1 - m$, with $m \in (0, 1)$, of a markup $\mu = \frac{\tau(1 + \tau)}{\kappa(3 + \tau)}$ ⁵. The case of $m = 0$ corresponds to no regulation (the brand-name drug producer is able to charge the optimal p_b), while the case of $m = 1$ corresponds to the strictest regulation possible (the price of the brand-name drug is set to the price of the generic version). Thus, the regulatory parameter m is a measure for the strictness of regulation.

Patient co-payments are not affected by the maximum price system and are still given as $c_i = \kappa p_i$.

⁵This structure allows to analyze different degrees of regulation explicitly.

For a given price cap, the generic producer's best-response function is $p_g^m = \frac{1}{2}p_b^m(1 - \tau)$. Equilibrium prices are

$$p_b^m = \frac{\tau(2 - m(1 + \tau))}{\kappa(3 + \tau)} \text{ and } p_g^m = \frac{\tau(2 - m(1 + \tau))(1 - \tau)}{2\kappa(3 + \tau)}. \quad (10)$$

Compared to the benchmark case of no regulation, both drug prices are lower under the maximum price system:

$$\begin{aligned} p_b - p_b^m &= \frac{\tau m(1 + \tau)}{\kappa(3 + \tau)} > 0 \\ p_g - p_g^m &= \frac{\tau m(1 + \tau)(1 - \tau)}{2\kappa(3 + \tau)} > 0. \end{aligned}$$

The brand-name price is set to a lower amount by the regulator. The generic producer has to lower his price in response to the lower brand-name price as well, as he has to compensate consumers for the lower (perceived) quality by pricing at a certain discount from a given brand-name price. This relationship is given by the generic producer's best-response function.

Equilibrium quantities are

$$q_b^m = \frac{4 + m(1 + \tau)^2}{2(3 + \tau)} \text{ and } q_g^m = \frac{2 - m(1 + \tau)}{2(3 + \tau)}. \quad (11)$$

The quantity of the brand-name drug is higher under the maximum price system, the quantity of the generic is lower:

$$q_b - q_b^m = -\frac{m(1 + \tau)^2}{2(3 + \tau)} < 0, \quad q_g - q_g^m = \frac{m(1 + \tau)}{2(3 + \tau)} > 0.$$

The brand-name drug is sold to more consumers under regulation, as the lower price makes it attractive also for consumers with an intermediate valuation θ who purchased the generic before. For the generic producer, this sales volume lost to the brand-name drug is larger than the volume gained from consumers who have not purchased before and now purchase the generic due to its lower price. That is, the consumer indifferent between the brand-name drug and the generic moves away from one by a larger distance than the consumer indifferent between the generic and not buying moves towards zero⁶.

Profits are given as

$$\Pi_b^m = \frac{\tau(2 - m(1 + \tau))(4 + m(\tau + 1)^2)}{2\kappa(3 + \tau)^2} \text{ and } \Pi_g^m = \frac{\tau(1 - \tau)(2 - m(1 + \tau))^2}{4\kappa(3 + \tau)^2}. \quad (12)$$

⁶The locations of indifferent consumers under the maximum price system are $\theta^{*m} = \frac{(2 - m(1 + \tau))(1 + \tau)}{2(3 + \tau)}$ and $\underline{\theta}^m = \frac{(2 - m(1 + \tau))\tau}{2(3 + \tau)}$, of which $\underline{\theta}^m$ is closer to its counterpart under no regulation than θ^{*m} is: $\theta^* - \theta^{*m} = \frac{m(1 + \tau)^2}{2(3 + \tau)} > \theta - \underline{\theta}^m = \frac{m\tau(1 + \tau)}{2(3 + \tau)}$.

Compared to the benchmark case of no regulation, both firms' profits are lower. For the brand-name producer, the profit-decreasing effect of a lower price exceeds the profit-increasing effect of a higher sales volume. The generic producer sells a lower quantity at a lower price.

3.3 Reference Price System

Consider now a reference price system. The reference price is a linear function of both drug prices⁷:

$$R = rp_g^r + (1-r)p_b^r, \quad (13)$$

where $r \in (0, 1)$ is an exogenous weight⁸. For $r = 1$, the reference price and consequently the reimbursement amount corresponds to the price of the generic, for $r = 0$, the reference price and reimbursement amount coincide with the price of the brand-name drug, which amounts to the benchmark case of no regulation. The reference price is determined endogenously⁹, which involves a reaction of the reference price to the firms' strategic response to the introduction of a reference price system¹⁰.

Patient co-payments are given as

$$c_b^r = \kappa R + (p_b^r - p_r^r) \text{ and } c_g^r = \kappa p_g^r. \quad (14)$$

An increase of the reference price has two effects on the total co-payment for the brand-name drug: On the one hand, the co-payment determined by the coinsurance rate and the reference price (κR) increases, on the other the difference between the sales price and the reference price ($p_b^r - R$) decreases for given market prices, as the reference price can be considered a subsidy (Mestre-Ferrándiz, 2003).

Demand functions are given as

$$q_b^r = 1 - \frac{((1-r)\kappa + r)(p_b^r - p_g^r)}{\tau} \text{ and } q_g^r = \frac{((1-r)\kappa + r)(p_b^r - p_g^r)}{\tau} - \frac{\kappa p_g^r}{1-\tau}. \quad (15)$$

⁷Being a convex combination of the two drugs' market prices, this reference price implies that the generic drug is available without any additional co-payment, whereas for the brand-name drug an additional co-payment applies. Thus, the reference price system can be considered to impose an additional, but avoidable co-payment (López-Casasnová & Puig-Junoy, 2000). In this model, consumers will have to trade off the additional co-payment against the (perceived) loss in quality, as the generic drug is associated with lower quality.

⁸Note that a specification of the reference price as a convex combination of both drug prices ($R = rp_g^r + (1-r)p_b^r$) is equivalent to a specification of the reference price as the generic price plus a fraction $(1-r)$ of the markup of the brand-name over the generic price ($R = p_g^r + (1-r)(p_b^r - p_g^r)$).

⁹See Brekke, Holmas & Straume 2008 for the different implications of exogenously and endogenously determined reference prices.

¹⁰Strictly speaking, the introduction of a reference price system causes firms to lower their prices, which in turn then decreases the reference price. This reaction then results in firms lowering their prices again.

Equilibrium prices are

$$\begin{aligned} p_b^r &= \frac{2\tau(\kappa + r(1 - \tau)(1 - \kappa))}{(\kappa + r(1 - \kappa))(\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))} \\ \text{and } p_g^r &= \frac{\tau(1 - \tau)}{\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa)}, \end{aligned} \quad (16)$$

which are both lower than in the no regulation case:

$$\begin{aligned} p_b - p_b^r &= \frac{2\tau r(1 - \kappa)(\kappa(3 + \tau^2) + 3r(1 - \tau)(1 - \kappa))}{\kappa(3 + \tau)(\kappa + r(1 - \kappa))(\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))} > 0 \\ p_g - p_g^r &= \frac{3\tau r(1 - \kappa)(1 - \tau)^2}{\kappa(3 + \tau)(\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))} > 0. \end{aligned}$$

The brand-name producer has to lower his price in order to counterbalance the effect of the increased co-payment. The generic producer then lowers his price in response to the lower brand-name price as well. Price elasticity of demand increases for both drugs:

$$\begin{aligned} \eta_b^r &= -\frac{(1 - r)\kappa + r}{\tau} \frac{p_b^r}{q_b^r} > -\frac{\kappa p_b}{\tau q_b} = \eta_b, \\ \eta_g^r &= -\frac{\kappa + r(1 - \tau)(1 - \kappa)}{\tau(1 - \tau)} \frac{p_g^r}{q_g^r} > -\frac{\kappa p_g}{\tau(1 - \tau) q_g} = \eta_g. \end{aligned}$$

Equilibrium quantities are given as

$$q_b^r = \frac{2(\kappa + r(1 - \tau)(1 - \kappa))}{\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa)} \quad \text{and} \quad q_g^r = \frac{(\kappa + r(1 - \tau)(1 - \kappa))}{\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa)}. \quad (17)$$

Both firms' quantities are higher than under no regulation:

$$\begin{aligned} q_b - q_b^r &= -\frac{2\tau r(1 - \kappa)(1 - \tau)}{(3 + \tau)(\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))} < 0, \\ q_g - q_g^r &= -\frac{\tau r(1 - \kappa)(1 - \tau)}{(3 + \tau)(\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))} < 0. \end{aligned}$$

The brand-name drug producer lowers his price by more than what would be needed to sell the same quantity as under no regulation. The generic producer attracts more consumers from lowering his price than he loses to the brand-name producer.

The reference price is given as

$$R = \frac{\tau((2 - r)(\kappa + r(1 - \kappa)) - (2 - (\kappa + r(1 - \kappa))))}{(\kappa + r(1 - \kappa))(\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))}. \quad (18)$$

Firms' profits are

$$\begin{aligned}\Pi_b^r &= \frac{4\tau(\kappa + r(1 - \tau)(1 - \kappa))^2}{(\kappa + r(1 - \kappa))(\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))^2} \\ \text{and } \Pi_g^r &= \frac{\tau(1 - \tau)(\kappa + r(1 - \tau)(1 - \kappa))}{(\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))^2}.\end{aligned}\tag{19}$$

Both firms' profits are lower under the reference price system, as the profit-decreasing effect of lower prices dominates the profit-increasing effect of higher quantities.

4 Policy Objectives in Regulation

The two regulatory instruments analyzed in this paper, direct price control and reimbursement regulation, are policy alternatives that are *mutually exclusive*. The choice of a regulatory instrument is determined by the objectives of regulators (Maynard & Bloor, 2003). For example, other than the intention to reduce public expenditure, objectives commonly articulated by policymakers are to improve access to pharmaceuticals, and to stimulate competition. Whether an instrument is able to achieve these objectives and to outperform the alternatives, determines which instrument is chosen from a set of alternatives.

Two main factors drive the performance of the two regulatory systems with respect to the health policy objectives: Price reductions and the reimbursement amount. For a given reimbursement amount, higher price reductions result in lower public pharmaceutical expenditure, lower financial exposure of patients and accordingly better access to pharmaceuticals. A lower reimbursement amount at given price reductions leads to lower health expenditure, but higher financial exposure of patients and worse access to pharmaceuticals. The next subsections present a visualization of these results, proofs can be found in the Appendix.

4.1 Price Reductions

When comparing price reductions under both regulatory systems, two concepts have to be distinguished: The *regulatory degree* determines what percentage of the markup of the brand-name over the generic is included in the price cap and/or in the reimbursement limit under the reference price system respectively. The *regulatory price* specifies the price cap or reimbursement limit that is realized eventually. Under the maximum price system, these two concepts are equivalent: If e.g. the regulatory body allows the brand-name producer to charge 50 % of the markup over the generic, then this corresponds to setting a price cap including 50 % of this markup. Under the reference price system, the endogenous specification of the reference price (the reference price is not defined in terms of unregulated prices, but is instead a function of (current) market prices) results in a mismatch between the two concepts: If e.g. the regulatory body sets a reimbursement limit covering 50 % of the markup of brand-name over the generic, then an exogenous specification would result in a reference price including 50 % of this markup, but the

endogenous specification yields a lower reference price, as it captures the strategic price decrease of both firms following the introduction of a reimbursement limit. The introduction of a reference price system causes firms to lower their prices, which in turn then decreases the reference price and consequently, the realized reference price is lower than what is specified by the degree of regulation. The endogenous specification of the reference price is an important factor driving price reductions under the reference price system: Starting from a certain regulatory degree it increases the strictness of regulation by generating a lower regulatory price.

In addition, two other factors determine relative price reductions under the two regulatory systems: First, the reference price generates a higher price elasticity of demand for the brand-name drug and thus a higher incentive for the brand-name producer to lower the price. Second, opposed to this, the regulatory price corresponds to the price of the brand-name drug under the maximum price system per definition, whereas under the reference price system, free pricing enables the brand-name producer to set a price above the regulatory price to skim off additional willingness to pay¹¹. Based on an identical regulatory degree, the higher price elasticity and the dynamics of the endogenous specification of the reference price result in higher price reductions for the brand-name under reference pricing, whereas, for a given regulatory price, price reductions are higher under the maximum price system due to free pricing under the reference price system.

Figure 1 illustrates the comparison of brand-name prices under both regulatory systems for $\tau = 0.5$ and $\kappa = 0.1$. The (dotted) 45°-line denotes identical regulatory degrees, all combinations of r and m that result in identical percentages of the markup of the brand-name over the generic included in the price cap under the maximum price system and in the reimbursement limit under the reference price system respectively.

The (very left) solid line denotes identical regulatory prices, all combinations of r and m that result in the same price set by the regulatory authority. That is, along this line, the price cap under the maximum price system is identical to the reimbursement limit under the reference price system. The slope of this line depicting identical regulatory prices is greater than 1 due to the endogenous specification of the reference price, which captures the firms' reaction to the reference price, i.e. the price decrease. This increases the strictness of regulation beyond the measure specified by the regulatory degree. For a higher r , the slope becomes smaller. The price for the brand-name drug decreases by more than the price of the generic for a higher r ($\frac{\partial(p_b^r/p_g^r)}{\partial r} < 0$), but is included in the reference price to a lower extent (a higher r gives less weight to the brand-name relative to the generic). Compared to the endogenous specification of the reference price, the higher weight of the lower-priced generic in the reference price becomes a relatively more important factor in decreasing the reference price (but has a weaker impact than the aforementioned). Note that the (dotted) 45°-line denoting identical regulatory degrees depicts both factors determining price reductions under the reference price system – the increase

¹¹Note that also the endogenous specification of the reference price prevents the brand-name producer from setting a price equal or below the reference price. But also for an exogenously determined reference price the brand-name price above the reference price is profit maximizing, as it allows the brand-name producer to skim off additional willingness to pay.

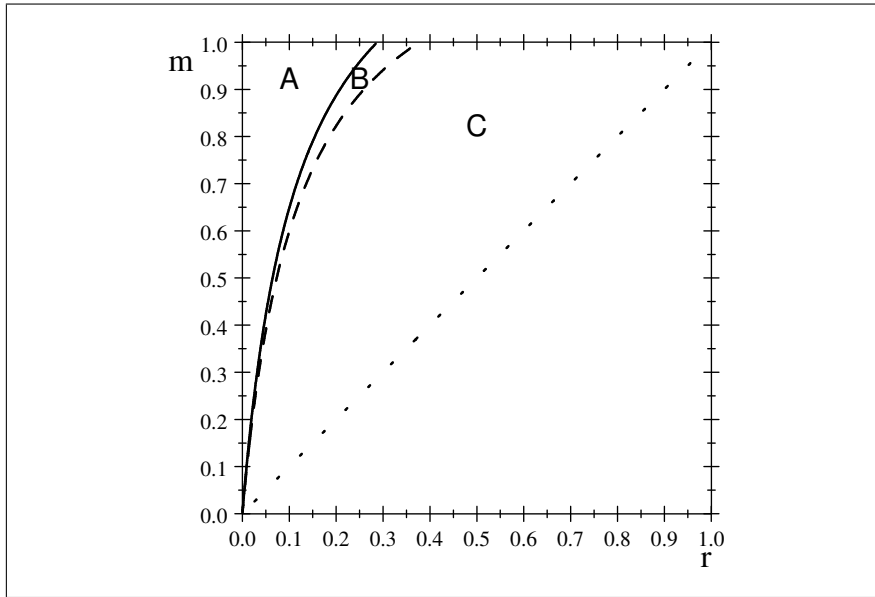


Figure 1: Figure 1: Brand-name Price, $\tau = 0.5$, $\kappa = 0.1$

of strictness due to the endogenous specification of the reference price and free price setting, whereas the (very left) solid line denoting identical regulatory prices ignores the effect from the endogenous specification of the reference price and focuses on the effect of free price setting. The dashed line denotes represents all combinations of regulatory parameters that result in identical prices for the brand-name drug. To the left of this dashed line (in A and B), price reductions are higher under the maximum price system. To the right of dashed line (in C), price reductions are higher under the reference price system.

The 45°-line denoting identical regulatory degrees runs to the right of the dashed line, i.e. for identical percentages of the markup of the brand-name over the generic permitted under the two regulatory systems, price reductions are higher under the reference price system. This is due to the endogenous specification of the reference price. Also for area C, where the regulatory degree is moderately higher under the maximum price system, price reductions are higher under the reference system. As the effect of endogenous specification of the reference price is weaker for a high r and accordingly the price of brand-name drug decreases less, the difference between the 45°-line and the dashed line becomes smaller for a high r .

The solid line denoting identical regulatory prices runs to the left of the dashed line, i.e. for identical regulatory prices, price reductions are higher under the maximum price system. Under the maximum price system, the regulatory price corresponds to the price for the brand-name drug, whereas under the reference price system, the brand-name producer sets a price above the reference price. For a high r , this difference between brand-name price and reference price becomes larger. Under the maximum price system, a decrease in the regulatory price is equivalent to a (commensurate) decrease in the price for the brand-name drug. Under the reference price

system, a decrease of the regulatory price results in a less than proportional price reduction for the brand-name drug. Also for area B, where the regulatory price is moderately lower under the reference price system, price reductions are higher under the maximum price system.

These results hold independently of the degree of product differentiation: Based on the regulatory degree, price reductions are higher under the reference price system; whereas based on the regulatory price, price reductions are higher under the maximum price system.

For a higher degree of product differentiation, i.e. if the brand-name drug and the generic are more remote substitutes, the higher willingness to pay for the brand-name drug allows the brand-name producer to set the price further above the reference price. This weakens the effect from the endogenous specification of the reference price and the brand-name price decreases less under the reference price. This makes the dashed line denoting identical prices moving towards the 45°-line denoting identical regulatory degrees and away from the solid line denoting identical regulatory prices.

4.2 Expenditure Reduction

Both regulatory instruments reduce pharmaceutical expenditure. Under the maximum price system, the lower prices of both drugs reduce expenditure to

$$E^m = (1 - \kappa) (p_b^m q_b^m + p_g^m q_g^m), \quad E - E^m > 0, \quad (20)$$

and under the reference price system, both lower prices and a lower basis for reimbursement (not the market price, but the reference price is the basis for reimbursement) contribute to lower expenditure of:

$$E^r = (1 - \kappa) (Rq_b^r + p_g^r q_g^r), \quad E - E^r > 0. \quad (21)$$

For a direct comparison of the two regulatory instruments with respect to their performance in expenditure reduction, two factors are crucial: Price reductions and the reimbursement amount. Whether price reductions are higher under the maximum price system or the reference price system, depends on the standard of comparison¹². The reimbursement amount is lower under the reference price system (the brand-name drug is reimbursed based on reference price instead of the higher market price). The latter effect dominates and independent of the standard of comparison, expenditure is lower under the reference price system. This also implies that for given prices, expenditure is lower under the reference price system¹³.

Consider Figure 2 for a visualization of the comparison of expenditure under both systems for $\tau = 0.5$ and $\kappa = 0.1$. The dotted line denotes all combinations of the regulatory parameters

¹²Based on the regulatory degree, price reductions are higher under the reference price system; whereas based on the regulatory price, price reductions are higher under the maximum price system.

¹³Two other factors point in the opposite direction: the reference price system exhibits a larger generic share and a lower brand-name premium, that is, a larger generic volume at a higher relative price is included in the expenditure under the reference price system. But these latter effects are dominated by the expenditure-reducing effect from a lower reimbursement amount.

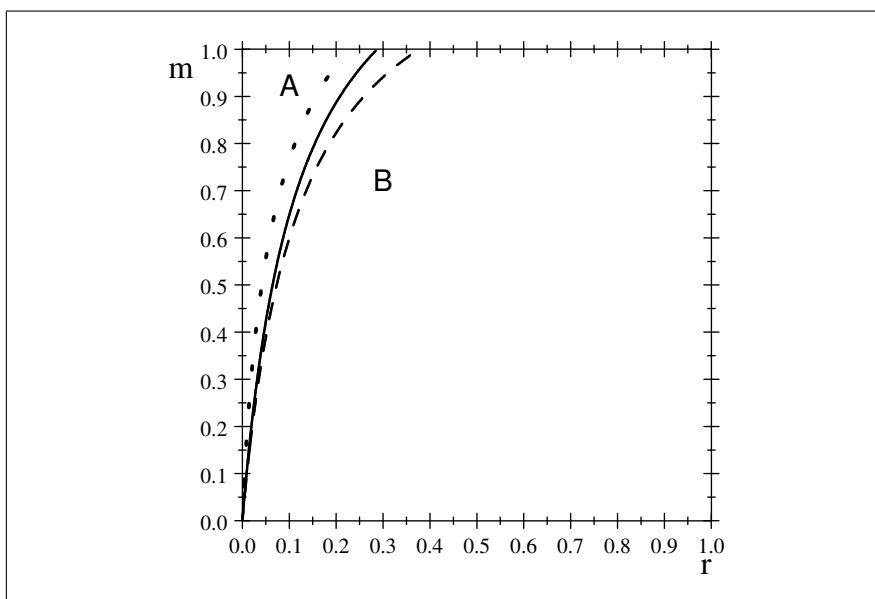


Figure 2: Expenditure, $\tau = 0.5$, $\kappa = 0.1$

r and m that result in identical expenditure under the maximum price and the reference price system. To the right of this line (in area B), expenditure is higher under the maximum price system, to its left (in area A), expenditure is higher under the reference price system.

The slope of this line is greater than 1. This implies that, based on the same point of initial expenditure, an identical decrease of expenditure under the maximum price system and the reference price system is associated with a higher decrease of the price ceiling under the maximum price system than with the decrease of the reimbursement amount under the reference price system. On the contrary, a small decrease of r , i.e. a small raise of the reimbursement limit, already causes the same increase in expenditure than a higher increase in m under the maximum price system would yield.

The solid line denoting all combinations of r and m that result in the same price set by the regulatory authority runs to the left of the dotted line denoting identical expenditure. This is, comparing expenditures under both systems for identical regulatory prices, i.e. an identical price cap under the maximum price system and reimbursement limit under the reference price system, the reference price system reduces expenditure to a greater extent because of a lower reimbursement amount despite higher price reductions under the maximum price system.

For identical prices (dashed line), expenditure is lower under the reference price system, as the reimbursement amount is lower. Put differently, for identical expenditure under the maximum price system and the reference price system, the reference price system allows for higher market prices of brand-name drugs.

Independent of the degree of product differentiation, the reference price system reduces expenditure to a larger extent than the maximum price system.

For higher degrees of product differentiation, the advantage of the reference price system in reducing expenditure is higher for identical prices. That is, the relative importance of price reductions decreases, whereas the effect from a lower reimbursement amount increases.

Proposition 1 summarizes the performance of both regulatory instruments with respect to the reduction of expenditure:

Proposition 1 *Suppose that price reductions for the brand-name drug are identical under the maximum price system and the reference price system. Then public pharmaceutical expenditure is lower under the reference price system.*

4.3 Equity and Access

Equity, the concept of fairness and justice, is one of the major concerns in health policy (Hurley, 2003). Two dimensions of equity are relevant when comparing the two regulatory instruments: financial exposure and access. First, the analysis of out-of-pocket expenditure under the different scenarios illustrates financial exposure of patients. Under the maximum price system, co-payments rules do not change; consequently, consumers benefit fully from lower prices. The reference price system, however, introduces an additional co-payment element, patients also have to pay the difference between the market price and reference price. Therefore, out-of-pocket expenditure under the reference price system needs to be compared carefully with payments under no regulation. Second, the analysis of quantities and the uncovered part of the market (consumers with a low valuation θ) gives an idea of access to pharmaceuticals. In general, lower drug prices improve access, as also consumers with lower valuation can now afford the generic. The concept of consumer surplus as a measure for well-being in the aggregate combines the aspects of financial exposure and access.

4.3.1 Co-payments

Both regulatory instruments reduce copayments. Under the maximum price system, lower drug prices reduce co-payments

$$\begin{aligned} c_b^m &= \kappa p_b^m, c_b - c_b^m > 0, \\ c_g^m &= \kappa p_g^m, c_g - c_g^m > 0. \end{aligned} \tag{22}$$

Co-payments for the brand-name drug and the generic, respectively, under the reference price system are given as:

$$\begin{aligned} c_b^r &= \kappa R + p_b^r - R, c_b - c_b^r > 0, \\ c_g^r &= \kappa p_g^r, c_g - c_g^r > 0. \end{aligned} \tag{23}$$

which are both lower than under no regulation. The co-payment-decreasing effect of a lower

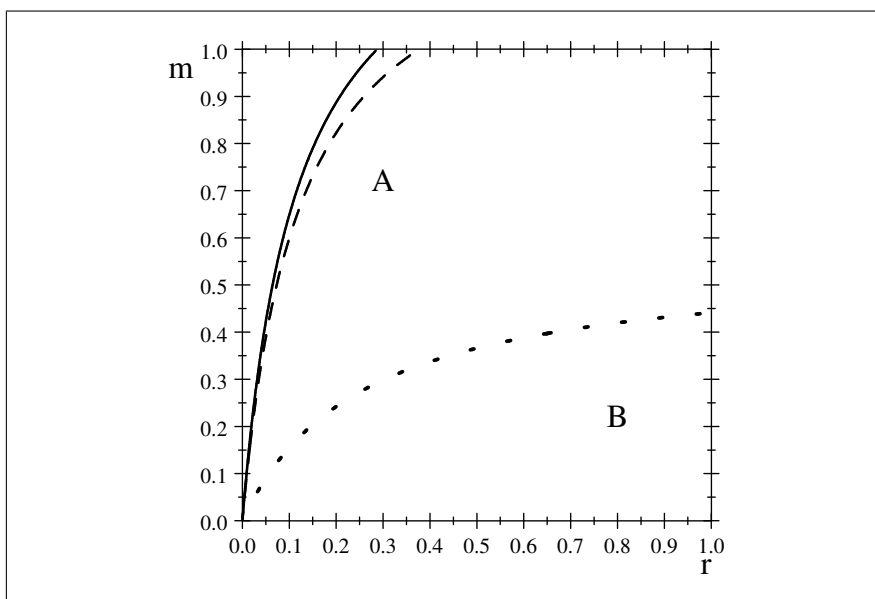


Figure 3: Figure 3: Brand-Name Copayment, $\tau = 0.5$, $\kappa = 0.1$

brand-name price dominates the co-payment-increasing effect of a lower reimbursement amount (the reference price instead of the market price is the basis for reimbursement). The co-payment for the generic is unambiguously lower under the reference price system, as the drug price is lower and co-payment rules do not change.

When comparing co-payments for the brand-name drug directly, two factors determine, whether out-of-pocket expenditure is higher under the maximum price or the reference price system: First, for identical regulatory prices, price reductions are higher under the maximum price system. The application of coinsurance rates implies that lower drug prices translate to lower co-payments. Second, in the reference price system health insurance reimburses the brand-name drug based on the reference price. This involves an additional co-payment element – the difference between the market price of the brand-name drug and the reference price. Both factors result in a higher co-payment for the brand-name drug under the reference price system, as illustrated by Figure 3 for $\tau = 0.5$ and $\kappa = 0.1$. The dotted line denotes all combinations of the regulatory parameters r and m that give identical co-payments for the brand-name drug under the maximum price and the reference price system. To the left of this line (in area A), out-of-pocket expenditure is higher under the reference price system, to its right (in area B), out-of-pocket expenditure is higher under the maximum price system.

The solid line denoting identical regulatory prices runs to the left of the dotted line. That is, both lower price reductions under the reference price system and a lower reimbursement amount under the reference price system result in higher co-payments under the reference price system.

The dashed line denoting identical prices visualizes the isolated effect from a changed reim-

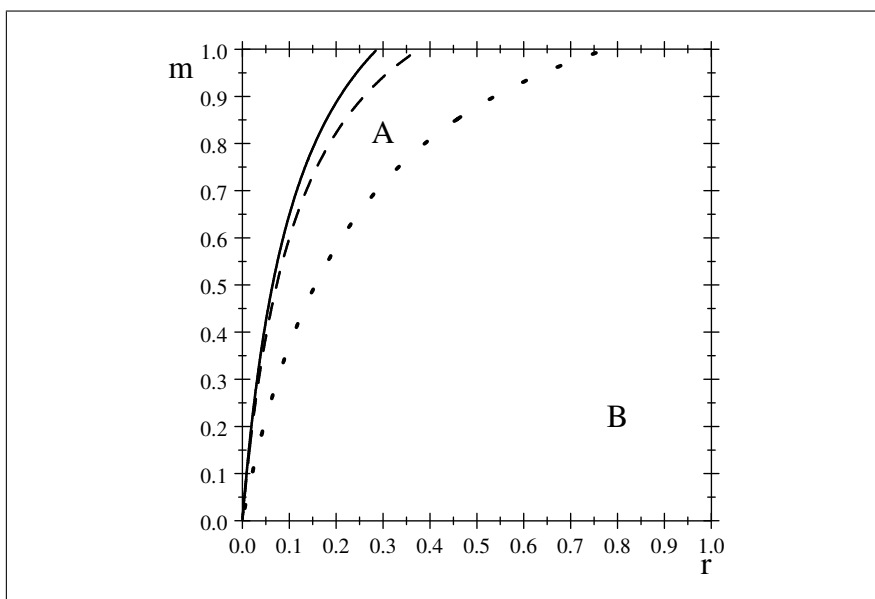


Figure 4: Figure 4: Generic Copayment, $\tau = 0.5$, $\kappa = 0.1$

bursement amount. A lower reimbursement amount makes the co-payment for the brand-name drug always higher under the reference price system. This is illustrated by the dashed line denoting identical prices running to the left to the dotted line.

Also for other degrees of product differentiation/Independent of the degree of product differentiation, the co-payment for the brand-name drug is higher under the reference price system. Similar to the comparison of relative performance in decreasing expenditure, the effect of a lower reimbursement amount becomes more important and the effect of price reductions is relatively less important for a higher degree of product differentiation.

Consider Figure 4 for a visualization of the comparison of co-payments for the generic under both systems for $\tau = 0.5$ and $\kappa = 0.1$.

The dotted line denotes all combinations of the regulatory parameters r and m that give identical co-payments for the generic under the maximum price and the reference price system. To the right of this line (in area B), co-payments for the generic are higher under the maximum price system. To its left (in area A), co-payments for the generic are higher under the reference price system. Since co-payments are directly proportional to market prices, the dotted line also represents all combinations of regulatory parameters that result in identical prices for the generic under both systems.

For identical regulatory prices, free pricing causes the price for the brand-name drug to be higher under the reference price system. Under the maximum price system, the generic producer prices at a higher discount from a given brand-name price than under the reference price system¹⁴.

¹⁴Note that under the maximum price system, the best response function of the generic producer is given as $p_g^m = \frac{1}{2}p_b^m(1 - \tau)$, whereas under the reference price system, the best response function of the generic producer

Conversely, this implies that the brand-name premium is lower under the reference price system. That is, for identical regulatory prices, the difference between prices under the maximum price system and the reference price system is higher for generic prices as compared to brand-name prices. This is illustrated by the dotted line depicting identical copayments running to the right of the dashed line depicting identical prices. This implies that for identical regulatory prices and for identical prices of the brand-name drug, prices for the generic and, consequently, co-payments for the generic are lower under the maximum price system.

For a higher degree of product differentiation, the discount of the generic price from the brand-name price increases more under the maximum price system than under the reference price system. This implies that the relative advantage of the maximum price system in reducing out-of-pocket expenditure for generic users is higher for a higher degree of product differentiation.

That is, co-payments for both drugs and thus financial exposure of patients to costs of pharmaceuticals are lower under the maximum price system.

4.3.2 Total Quantity (Access)

Under both regulatory instruments, the total quantity increases.

Under the maximum price system, the effect from a higher brand-name sales volume exceeds the effect of a lower generic quantity so that the quantity of the drug increases to

$$Q^m = q_b^m + q_g^m, Q - Q^m < 0. \quad (24)$$

Under the reference price system, more is sold of both the brand-name drug and the generic and correspondingly, the total quantity is higher :

$$Q^r = q_b^r + q_g^r, Q - Q^r < 0. \quad (25)$$

Thus, as the quantity increases under both the maximum price and the reference price system, both regulatory instruments can be considered to improve access to pharmaceuticals.

When compared directly, three factors determine whether total quantity is higher under the maximum price or the reference price system. First, for identical regulatory prices, price reductions are higher under the maximum price system. Lower prices imply that more consumers are able and willing to buy the drug, hence higher price reductions translate to a higher quantity. Second, for identical price reductions, the quantity of the brand-name drug is higher under the maximum price system, since from a consumer perspective, less has to be paid for the drug under the maximum price system. Third, the generic quantity is higher under the reference price system. The first two effects exceed the latter and total quantity is higher under the maximum system.

is given as $p_g^r = \frac{1}{2}p_b^r(1 - \tau) \frac{((1-r)\kappa+r)}{(\kappa+r(1-\tau)(1-\kappa))} \cdot \frac{((1-r)\kappa+r)}{(\kappa+r(1-\tau)(1-\kappa))} > 1$.

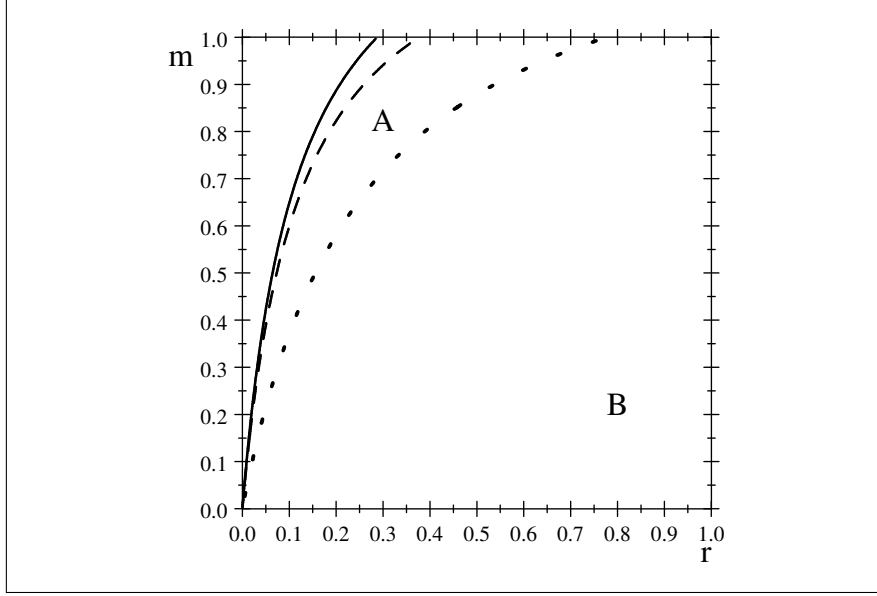


Figure 5: Figure 5: Quantity, $\tau = 0.5$, $\kappa = 0.1$

Consider Figure 5 for a visualization for $\tau = 0.5$ and $\kappa = 0.1$. The dotted line denotes all combinations of the regulatory parameters r and m that give identical total sales volumes of both versions of the drug under the maximum price and the reference price system. To the right of this line (in area B), the total quantity of the drug is higher under the reference price system. To its left (in area A), the total quantity of the drug is higher under the maximum price system. The dotted line runs to the right of both the solid and the dashed line i.e. for identical regulatory prices and for identical prices of the brand-name, total quantity is higher under the maximum price system. This also holds independent of the degree of product differentiation.

4.3.3 Consumer Surplus

Under the maximum price system, consumer surplus for brand-name users is higher than under no regulation, as a larger quantity is consumed at a lower price:

$$CS_b^m = \int_{\theta^*}^1 (\theta - \kappa p_b^m) d\theta, CS_b - CS_b^m < 0. \quad (26)$$

Consumer surplus for generic users is lower than in the case of no regulation, as the effect of a lower quantity dominates the effect of a lower price on consumer surplus:

$$CS_g^m = \int_{\underline{\theta}}^{\theta^*} (\theta(1 - \tau) - \kappa p_g^m) d\theta, CS_g - CS_g^m > 0. \quad (27)$$

Thus, brand-name users benefit from the maximum price system, generic users lose from it.

Under the reference price system, consumer surplus for both brand-name users and generic users is higher than under no regulation, since drug prices are lower and higher quantities are consumed:

$$\begin{aligned}
CS_b^r &= \int_{\theta^*}^1 (\theta - \kappa R - (p_b^r - R)) d\theta, \quad CS_b - CS_b^r < 0, \\
CS_g^r &= \int_{\underline{\theta}}^{\theta^*} (\theta(1 - \tau) - \kappa p_g^r) d\theta, \quad CS_g - CS_g^r < 0.
\end{aligned} \tag{28}$$

Both groups of consumers benefit from the reference price system.

Consumer surplus for brand-name users is higher under the maximum price, as the co-payment for the brand-name drug is lower and the quantity is higher. For generic users, consumer surplus is higher under the reference price system, the co-payment for the generic is lower under the maximum price system, but the quantity is higher under the reference price system.

Proposition 2 summarizes the performance of both regulatory instruments with respect to distributive objectives:

Proposition 2 *Suppose that price reductions of the brand-name drug are identical under the maximum price system and the reference price system. Then financial exposure of patients is lower and access to pharmaceuticals is higher under the maximum price system. Consumer surplus for brand-name users is higher under the maximum price system, consumer surplus for generic users is higher under the reference price system.*

4.4 Competition in Pharmaceutical Markets

The degree of competition between the brand-name producer and the generic producer is determined by the degree of product differentiation to a large extent, as it allows the brand-name producer to charge a higher price while maintaining a significant market share. The more remote substitutes the two versions of the drug are, the higher τ is, the more will prices diverge. In other words, decreasing the degree of product differentiation will stimulate competition between the two firms. For a given τ , regulation can also have an effect on competition. Against the background of the benchmark case of perfect competition, when $\tau = 0$ and both firms price at marginal cost, the analysis of competition between the two firms has several dimensions: First, the existence and extent of a brand-name price premium indicates whether both versions are considered and treated as close or remote substitutes. Note that both regulatory instruments assume equivalence of the brand-name and generic version. Second, the generic market share illustrates the extent to which the generic producer can prevail against the brand-name producer and generic competition occurs. Third, the relationship between profits and the degree of product differentiation gives an idea of incentives for firms to differentiate their products and to gain a competitive advantage. As higher product differentiation amounts to a lower degree of competition, this could be viewed as an anticompetitive behavior.

4.4.1 Brand-name Premium

Under the maximum price system, the brand-name price premium is the same as under no regulation:

$$\frac{p_b^m}{p_g^m} = \frac{p_b}{p_g}. \quad (29)$$

That is, price reductions for the brand-name drug are as high as for the generic drug.

Under the reference price system, the brand-name price premium is lower than under no regulation

$$\frac{p_b^r}{p_g^r} < \frac{p_b}{p_g}. \quad (30)$$

Reference pricing reduces the brand-name price to a larger extent than the generic price. This is due to higher price elasticity of demand for the brand-name price.

4.4.2 Generic Market Share

Under the maximum price, the generic market share is lower than under no regulation:

$$\frac{q_g^m}{Q^m} < \frac{q_g}{Q}. \quad (31)$$

That is, by increasing the brand-name quantity and decreasing the generic quantity, the maximum price system decreases the generic market share and accordingly, it weakens generic competition.

Under the reference price system, the generic market share is the same as under no regulation:

$$\frac{q_g^r}{Q^r} = \frac{q_g}{Q}. \quad (32)$$

Thus, under the reference price system, brand-name and generic quantity increase by the same amount. Generic competition is not intensified under the reference price system.

4.4.3 Incentive for Product Differentiation

If the market is unregulated, the profit for the brand-name firm increases with the degree of product differentiation:

$$\frac{\partial \Pi_b}{\partial \tau} > 0. \quad (33)$$

Hence, there is an incentive for the brand-name producer to raise its profit by raising the degree of product differentiation. Generic profit increases in τ , if τ is sufficiently low:

$$\frac{\partial \Pi_g}{\partial \tau} > 0 \text{ if } \tau < \tau^*.$$

This is, to some extent there is also incentive for the generic producer to raise τ . For a low degree of product differentiation, the positive strategic effect exceeds the negative direct effect. A certain degree of product differentiation allows the generic producer to attract additional consumers with a low valuation, but also forces it to lower its price.

Both regulatory systems reduce the incentive to raise τ for sufficiently strict regulation. Both profits increase in τ for a sufficiently low degree of regulation:

$$\begin{aligned} \frac{\partial \Pi_b^m}{\partial \tau} &< 0, \text{ if } m > m_b^*, \quad \frac{\partial \Pi_g^m}{\partial \tau} < 0, \text{ if } m > m_g^*, \\ \frac{\partial \Pi_b^r}{\partial \tau} &< 0, \text{ if } r > r_b^*, \quad \frac{\partial \Pi_g^r}{\partial \tau} < 0, \text{ if } r > r_g^*. \end{aligned}$$

Proposition 3 summarizes the performance of both regulatory instruments with respect to stimulation of competition:

Proposition 3 *The maximum price system does not change the brand-name price premium and results in a lower generic market share. The reference price system reduces the brand-name price premium and increases the generic quantity, but does not change the generic market share. Both regulatory instruments reduce the incentive for firms to increase product differentiation.*

5 Welfare Analysis

This section examines the welfare effects of the two regulatory instruments. Welfare is given as the sum of consumer surplus for the brand-name and generic users, respectively, and profits for the two firms net of public pharmaceutical expenditure:

$$W = CS_b + CS_g + \Pi_b + \Pi_g - E. \quad (34)$$

Both regulatory instruments increase welfare:

$$W - W^m < 0, \quad W - W^r < 0. \quad (35)$$

When comparing welfare effects for the two regulatory instruments directly, the performance with respect to the above-mentioned health policy objectives determines, whether welfare is higher under the maximum price or the reference price system: Consumer surplus for brand-name users is higher under the maximum price system, while consumer surplus for generic users is higher under the reference price system. Total profits are higher under the maximum price system. Public pharmaceutical expenditure is lower under the reference price system. The effect of the maximum price system with respect to increasing consumer surplus for brand-name users and minimizing losses for firms exceeds the effect of the reference price system with respect to increasing consumer surplus for generic users and decreasing public pharmaceutical expenditure. Total welfare is higher under the maximum price system.

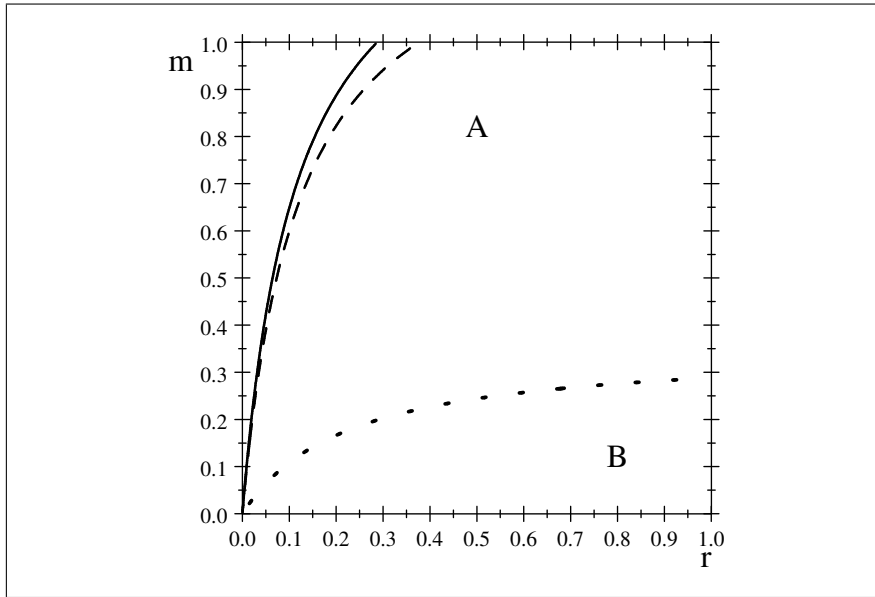


Figure 6: Figure 6: Welfare, $\tau = 0.5$

Consider Figure 6 for a visualization of the comparison of welfare under both systems for $\tau = 0.5$ and $\kappa = 0.1$. The dotted line denotes all combinations of the regulatory parameters r and m that result in identical total welfare under the maximum price and the reference price system. To the right of this line (in area B), welfare is higher under the reference price system, to its left (in area A), welfare is higher under the maximum price system.

The dotted line runs to the right of both the solid and the dashed line, i.e. for identical regulatory prices and for identical prices of the brand-name, total welfare is higher under the maximum price system. This holds independent of the degree of product differentiation.

Taking marginal cost of raising public funds into account corresponds to giving a higher weight to public pharmaceutical expenditure. This shifts the result of the welfare comparison in favor of the reference price system, since the reference price system reduces public pharmaceutical expenditure to a larger extent. Proposition 4 summarizes the performance of both regulatory instruments with respect to welfare:

Proposition 4 *Suppose that price reductions of the brand-name drug are identical under the maximum price system and the reference price system. Then welfare is higher under the maximum price system.*

6 Conclusion

In the model presented in this paper both the maximum price and the reference price system result in a reduction of drug prices and pharmaceutical expenditure, as intended by regulators.

Both instruments reduce financial exposure of patients and improve access to pharmaceuticals.

Under the reference price system, price reductions for the brand-name drug are driven by the endogenous specification of the reference price, which generates further price decreases by capturing the firms' strategic response to a reimbursement limit, and the pricing setting which enables the brand-name producer to skim off additional willingness to pay by setting a price above the reference price. The first factor generates higher price reductions under the reference price system for identical regulatory degrees, while the latter factor gives rise to lower price reductions as compared to the maximum price system for identical regulatory prices.

For identical price reductions of the brand-name drug, the lower reimbursement amount under the reference price system results in lower health expenditure, but higher financial exposure of patients. Access to pharmaceuticals is better under the maximum price system, although the generic quantity is higher under the reference price system. In the aggregate, consumer surplus for brand-name users is higher under the maximum price system, whereas consumer surplus for generic users is higher under the reference price system.

Consequently, there is a trade-off between important health policy objectives: The reference price system may be more appropriate to reduce public pharmaceutical expenditure or stimulate competition, but the maximum price system performs better for distributive objectives, such as limiting financial exposure of patients and guaranteeing access to pharmaceuticals. Total welfare is higher under the maximum price system. If transfers from patients to health insurance are possible and acceptable, the conflict between expenditure reduction and distributive objectives can be resolved and the maximum price system is preferable.

In general, if both versions of the drug were considered equivalent and, accordingly, perfect substitutes, all health policy objectives could easily be achieved. Perfect competition would reduce public expenditure, minimize financial exposure of patients and maximize access to pharmaceuticals. Consequently, the main health policy challenge is to reduce the degree of product differentiation. With respect to objective product differentiation, this corresponds to reducing permitted bandwidths of equivalence of additives and the degree of bioavailability. In addition, information of the public and mandatory substitution as means for patients to gather experience with generics could help to reduce subjective product differentiation. However, it has to be considered that substitution is problematic in some classes of drugs, such as antiepileptics, as the optimal dose has to be determined at the individual patient level and divergent permitted degrees of bioavailability harm therapeutic success (Hopf, 2002). Adjustment costs or health costs may emerge, when regulation reduces compliance.

The long-term effects of pharmaceutical regulation are subject to further research. In Germany, the introduction of the reference price system in 1989 has reduced public pharmaceutical expenditure only in the following years. As a consequence, further regulatory instruments were added.

Furthermore, the impact of lower profits on the incentive to invest (in quality) or on market entry has to be studied further. If regulation reduces investments or inhibits entry, there is a

trade-off between the static gains from cost containment on the one hand and potential dynamic losses from lower quality or reduced competition on the other hand.

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Health Policy Objectives

Price Reductions

Identical regulatory prices

$$p_b^m = \frac{\tau(2-m(1+\tau))}{\kappa(3+\tau)} = \frac{\tau((2-r)(\kappa+r(1-\kappa)) - (2-(\kappa+r(1-\kappa)))\tau r)}{[\kappa+r(1-\kappa)][\kappa(3+\tau)+3r(1-\tau)(1-\kappa)]} = R$$

$$m = r \frac{6(\kappa+r(1-\tau)) - \kappa(r(9-10\tau) - \tau^2(2-r)) - \kappa^2(1-\tau)(3-\tau)(1-r)}{(\tau+1)[\kappa+r(1-\kappa)][\kappa(3+\tau)+3r(1-\tau)(1-\kappa)]}$$

Identical brand-name prices

$$p_b^m = \frac{\tau(2-m(1+\tau))}{\kappa(3+\tau)} = \frac{2\tau(\kappa+r(1-\tau)(1-\kappa))}{[\kappa+r(1-\kappa)][\kappa(3+\tau)+3r(1-\tau)(1-\kappa)]} = p_b^r$$

$$m = \frac{2\kappa r(1-\kappa)(\tau^2+3) + 6r^2(1-\kappa)^2(1-\tau)}{(1+\tau)[\kappa+r(1-\kappa)][\kappa(3+\tau)+3r(1-\tau)(1-\kappa)]}$$

6.1 Expenditure Reduction

If the pharmaceutical market remains unregulated, public pharmaceutical expenditure is given as the reimbursed fraction $(1-\kappa)$ of total expenditure:

$$E = (1-\kappa)(p_b q_b + p_g q_g) = \frac{\tau(1-\kappa)(5-\tau)}{\kappa(3+\tau)^2}.$$

Under the maximum price system, the lower prices of both drugs reduce expenditure to

$$E^m = (1-\kappa)(p_b^m q_b^m + p_g^m q_g^m)$$

$$= \frac{\tau(1-\kappa)[4(5-\tau) - 8m(1-\tau^2) - m^2(3\tau+1)(\tau+1)^2]}{4\kappa(3+\tau)^2}$$

and under the reference price system, both lower prices and a lower basis for reimbursement (not the market price, but the reference price is the basis for reimbursement) contribute to lower expenditure of:

$$E^r = (1-\kappa)(Rq_b^r + p_g^r q_g^r)$$

$$= \frac{\tau(1-\kappa)[\kappa+r(1-\tau)(1-\kappa)] \left[\begin{array}{l} \kappa(5-\tau) - \kappa r(7-3\tau) \\ + r(1-\tau)(5-2r(1-\kappa)) \end{array} \right]}{[\kappa+r(1-\kappa)][\kappa(3+\tau)+3r(1-\tau)(1-\kappa)]^2}.$$

Thus, both regulatory instruments succeed in reducing pharmaceutical expenditure:

$$E - E^m = \frac{\tau m (\tau + 1) (1 - \kappa) (8(1 - \tau) + m(3\tau + 1)(\tau + 1))}{4\kappa(3 + \tau)^2} > 0,$$

$$E - E^r = \tau \frac{(1 - \kappa)}{\kappa} \frac{\left[\begin{array}{l} \kappa r^2 (1 - \tau) (1 - \kappa) (90 - 27\tau + 28\tau^2 + 5\tau^3) \\ + \kappa^2 r (\tau + 3) (15 - 11\tau + 13\tau^2 - \tau^3) \\ - \kappa^3 r (\tau + 3) (9 - \tau) (1 - \tau)^2 \\ - 3\kappa^2 r^2 (1 - \tau)^2 (1 - \kappa) (18 - 5\tau - \tau^2) \\ + r^3 (1 - \tau)^2 (1 - \kappa)^2 9 (5 - \tau) \\ - \kappa r^3 (1 - \tau)^2 (1 - \kappa)^2 (27 - 21\tau - 2\tau^2) \end{array} \right]}{[3 + \tau]^2 [\kappa + r(1 - \kappa)] [\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa)]^2} > 0.$$

Assuming regulatory prices under the maximum price system and the reference price, public expenditure under the maximum price system can be written in terms of the regulatory parameter r as follows: system,

$$E^m(r) = \frac{\tau(1 - \kappa) \left[\begin{array}{l} 2r + \kappa(2 - 3r) \\ -r\tau(2 - \kappa) \\ -r^2(1 - \tau)(1 - \kappa) \end{array} \right] \left[\begin{array}{l} 2\kappa^2(5 - \tau) \\ -r\kappa(\kappa(3\tau - 7)(\tau - 3) - 2(-6\tau + 3\tau^2 + 11)) \\ + r^2(\tau - 1)(\kappa - 1)(-11\kappa + 3\kappa\tau + 12) \end{array} \right]}{4(\kappa + r(1 - \kappa))^2 (\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))^2}$$

For identical regulatory prices, public expenditure is lower under the reference price system:

$$E^m - E^r \Big|_{\hat{p}=R} = r\tau(1 - \kappa) \frac{\left[\begin{array}{l} 4\kappa^2(3\tau^2 + 1 - \kappa(\tau - 1)^2) \\ + r\kappa(4(1 - \tau)(3\tau^2 + 2) - 4\kappa(-3\tau^3 + 9\tau^2 - 7\tau + 5) + \kappa^2(11 - 3\tau)(\tau - 1)^2) \\ + 2r^2(1 - \tau)(1 - \kappa)(2(1 - \tau) - 2\kappa(4 - 3\tau + 3\tau^2) + \kappa^2(1 - \tau)(5 - 3\tau)) \\ - r^3(1 - \tau)^2(1 - \kappa)^2(4 - 3\kappa(1 - \tau)) \end{array} \right]}{4(\kappa + r(1 - \kappa))^2 (\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))^2} > 0$$

Assuming identical price reductions under the maximum price system and the reference price system, public expenditure under the maximum price system can be written in terms of the regulatory parameter r as follows:

$$E^m(r) = \tau \frac{(1 - \kappa) \left[\begin{array}{l} \kappa^3(5 - \tau) + 4\kappa^2 r(4 - 3\tau + \tau^2)(1 - \kappa) \\ + \kappa r^2(1 - \tau)(17 - 6\tau + 3\tau^2)(1 - \kappa)^2 + 6r^3(1 - \kappa)^3(1 - \tau)^2 \end{array} \right]}{[\kappa + r(1 - \kappa)]^2 [\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa)]^2}.$$

For identical price reductions, public expenditure is lower under the reference price system:

$$E^m - E^r \Big|_{p_b^m = p_b^r} = \frac{\tau r (1 - \kappa) \left[\begin{array}{c} \kappa^2 (1 + 3\tau^2 + \kappa (3\tau + 1) (1 - \tau)) \\ + \kappa r (1 - \kappa) (1 - \tau) (2 + 3\tau^2) \\ + \kappa^2 r (1 - \kappa) (4 + 2\tau - 5\tau^2 + 3\tau^3) \\ + r^2 (1 - \kappa)^2 (1 - \tau) (1 - \tau + \kappa (\tau + 5)) \\ + 2r^3 (1 - \kappa)^3 (1 - \tau)^2 \end{array} \right]}{[\kappa + r (1 - \kappa)]^2 [\kappa (3 + \tau) + 3r (1 - \tau) (1 - \kappa)]^2} > 0$$

6.2 Equity and Access

Out-of-pocket Expenditure/Co-payments

If the market is unregulated, co-payments for the brand-name drug and the generic, respectively, are:

$$c_b = \kappa p_b = \frac{2\tau}{3 + \tau} \text{ and } c_g = \kappa p_g = \frac{\tau (1 - \tau)}{3 + \tau}.$$

Under the maximum price system, lower drug prices reduce co-payments to

$$c_b^m = \frac{\tau (2 - m (1 + \tau))}{(3 + \tau)} \text{ and } c_g^m = \frac{\tau (2 - m (1 + \tau)) (1 - \tau)}{2 (3 + \tau)},$$

$$c_b - c_b^m > 0 \text{ and } c_g - c_g^m > 0.$$

Co-payments for the brand-name drug and the generic, respectively, under the reference price system are given as:

$$c_b^r = \kappa R + p_b^r - R = \frac{\tau (2\kappa + r (1 - \tau) (1 - \kappa))}{(\kappa (3 + \tau) + 3r (1 - \tau) (1 - \kappa))}$$

$$\text{and } c_g^r = \frac{\kappa \tau (1 - \tau)}{\kappa (3 + \tau) + 3r (1 - \tau) (1 - \kappa)},$$

$$c_b - c_b^r > 0 \text{ and } c_g - c_g^r > 0.$$

which are both lower than under no regulation.

Assuming identical regulatory prices under the maximum price system and the reference price system, the copayment for the brand-name drug under the maximum price system can be written in terms of the regulatory parameter r as follows:

$$c_b^m(r) = \kappa \frac{\tau (2\kappa + r (2(1 - \tau) - \kappa (3 - \tau)) - r^2 (1 - \tau) (1 - \kappa))}{(\kappa + r (1 - \kappa)) (\kappa (3 + \tau) + 3r (1 - \tau) (1 - \kappa))}.$$

Taking identical regulatory prices as a basis of comparison, the copayment for the brand-name

drug is lower under the maximum price system:

$$\begin{aligned} & c_b^m - c_b^r \big|_{\widehat{p}=R} \\ = & -r\tau \frac{(\kappa(1+\tau) + r(1-\tau)(1-\kappa))}{(\kappa+r(1-\kappa))(\kappa(3+\tau) + 3r(1-\tau)(1-\kappa))} < 0. \end{aligned}$$

Assuming identical price reductions under the maximum price system and the reference price system, the copayment for the brand-name drug under the maximum price system can be written in terms of the regulatory parameter r as follows:

$$c_b^m(r) = \frac{2\kappa\tau(\kappa+r(1-\tau)(1-\kappa))}{[\kappa+r(1-\kappa)][\kappa(3+\tau) + 3r(1-\tau)(1-\kappa)]}.$$

Taking identical price reductions as a basis of comparison, the copayment for the brand-name drug is lower under the maximum price system:

$$\begin{aligned} & c_b^m - c_b^r \big|_{p_b^m=p_b^r} \\ = & -\tau r \frac{(1-\kappa)(\kappa(1+\tau) + r(1-\tau)(1-\kappa))}{[\kappa+r(1-\kappa)][\kappa(3+\tau) + 3r(1-\tau)(1-\kappa)]} < 0. \end{aligned}$$

Assuming identical regulatory prices under the maximum price system and the reference price system, the copayment for the generic drug under the maximum price system can be written in terms of the regulatory parameter r as follows:

$$c_g^m(r) = \frac{\kappa\tau(1-\tau)(2\kappa+r(2(1-\tau)-\kappa(3-\tau))-r^2(1-\tau)(1-\kappa))}{2(\kappa+r(1-\kappa))(\kappa(3+\tau) + 3r(1-\tau)(1-\kappa))}.$$

Taking identical regulatory prices as a basis of comparison, the copayment for the generic drug is lower under the maximum price system:

$$\begin{aligned} & c_g^m - c_g^r \big|_{\widehat{p}=R} \\ = & -\frac{r\kappa\tau(1-\tau)(2\tau+\kappa(1-\tau) + r(1-\tau)(1-\kappa))}{2(\kappa+r(1-\kappa))(\kappa(3+\tau) + 3r(1-\tau)(1-\kappa))} < 0. \end{aligned}$$

Assuming identical price reductions under the maximum price system and the reference price system, the copayment for the generic drug under the maximum price system can be written in terms of the regulatory parameter r as follows:

$$c_g^m(r) = \frac{2\kappa\tau(1-\tau)(\tau+3)(\kappa+r(1-\tau)(1-\kappa))}{2(3+\tau)(\kappa+r(1-\kappa))(\kappa(3+\tau) + 3r(1-\tau)(1-\kappa))}.$$

Taking identical price reductions as a basis of comparison, the copayment for the generic drug

is lower under the maximum price system:

$$c_g^m - c_g^r \Big|_{p_b^m = p_b^r} = -\frac{\kappa\tau^2 r (1 - \kappa) (1 - \tau)}{(\kappa + r (1 - \kappa)) (\kappa (3 + \tau) + 3r (1 - \tau) (1 - \kappa))} < 0.$$

Total Quantity

If the market is unregulated, the total quantity of both versions of the drug is

$$Q = \frac{3}{3 + \tau}.$$

Under the maximum price system, the effect from a higher brand-name sales volume exceeds the effect of a lower generic quantity so that the quantity of the drug increases to

$$Q^m = \frac{6 + \tau m (1 + \tau)}{2(3 + \tau)}, \quad Q - Q^m = -\frac{\tau m (1 + \tau)}{2(3 + \tau)} < 0.$$

Under the reference price system, the total sales volume of both versions of the drug is

$$Q^r = \frac{3(\kappa + r(1 - \tau)(1 - \kappa))}{\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa)},$$

$$Q - Q^r = -\frac{3\tau r(1 - \tau)(1 - \kappa)}{(\tau + 3)(\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))} < 0.$$

Compared to the unregulated market, more is sold of both the brand-name drug and the generic.

Assuming identical regulatory prices under the maximum price system and the reference price system, total quantity under the maximum price system can be written in terms of the regulatory parameter r as follows:

$$Q^m(r) = \frac{(\tau + 3) [6\kappa^2 + r\kappa(2(6 - 3\tau + \tau^2) - \kappa(3 - \tau)(4 - \tau)) + r^2(1 - \tau)(1 - \kappa)(6(1 - \kappa) + \kappa\tau)]}{2(3 + \tau)(\kappa + r(1 - \kappa))(\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))}$$

Taking identical regulatory prices as a basis of comparison, total quantity is higher under the maximum price system:

$$Q^m - Q^r \Big|_{\hat{p}=R} = \frac{r\kappa\tau(r(1 - \tau)(1 - \kappa) + \kappa(1 - \tau) + 2\tau)}{2(\kappa + r(1 - \kappa))(\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))} > 0.$$

Assuming identical price reductions under the maximum price system and the reference price system, total quantity under the maximum price system can be written in terms of the regulatory

parameter r as follows:

$$Q^m(r) = \frac{\kappa\tau^2 r (1 - \kappa)}{[\kappa + r(1 - \kappa)][\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa)]}$$

Taking identical price reductions as a basis of comparison, total quantity is higher under the maximum price system:

$$\begin{aligned} & Q^m - Q^r \big|_{p_b^m = p_b^r} \\ &= \frac{\kappa\tau^2 r (1 - \kappa)}{[\kappa + r(1 - \kappa)][\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa)]} > 0. \end{aligned}$$

6.2.1 Consumer Surplus

If the market is not regulated, consumer surplus for the brand-name users is given as

$$CS_b = \int_{\theta^*}^1 (\theta - \kappa p_b) d\theta = \frac{2(2 - \tau)}{(\tau + 3)^2}$$

and for generic user as

$$CS_g = \int_{\underline{\theta}}^{\theta^*} (\theta(1 - \tau) - \kappa p_g) d\theta = \frac{(1 - \tau)}{2(\tau + 3)^2}.$$

Under the maximum price system, consumer surplus for the brand-name users is given as

$$CS_b^m = \int_{\theta^*}^1 (\theta - \kappa p_b^m) d\theta = \frac{[4(2 - \tau) - m(\tau + 1)(1 - 3\tau)][4 + m(\tau + 1)^2]}{8(\tau + 3)^2},$$

which is higher than in the benchmark case, as a larger quantity is consumed at a lower price:

$$CS_b - CS_b^m = -\frac{m(\tau + 1)[4(1 + 4\tau - \tau^2) - m(1 - 3\tau)(\tau + 1)^2]}{8(\tau + 3)^2} < 0.$$

Consumer surplus for generic users is given as

$$CS_g^m = \int_{\underline{\theta}}^{\theta^*} (\theta(1 - \tau) - \kappa p_g^m) d\theta = \frac{(1 - \tau)(2 - m(1 + \tau))^2}{8(\tau + 3)^2},$$

which is lower than in the case of no regulation, as the effect of a lower quantity dominates the effect of a lower price on consumer surplus:

$$CS_g - CS_g^m = \frac{m(1 - \tau^2)(4 - m(1 + \tau))}{8(\tau + 3)^2} > 0.$$

Under the reference price system, consumer surplus for both brand-name users and generic users is higher than under no regulation, since drug prices are lower and higher quantities are consumed:

$$CS_b^r = \int_{\theta^*}^1 (\theta - \kappa R - (p_b^r - R)) d\theta = \frac{2(2-\tau)(\kappa + r(1-\tau)(1-\kappa))^2}{[\kappa(3+\tau) + 3r(1-\tau)(1-\kappa)]^2},$$

$$CS_b - CS_b^r = -\frac{2\tau r(1-\kappa)(1-\tau)(2-\tau) \left[\frac{2\kappa(\tau+3)}{+r(1-\kappa)(6+\tau)(1-\tau)} \right]}{(\tau+3)^2 [\kappa(3+\tau) + 3r(1-\tau)(1-\kappa)]^2} < 0$$

$$CS_g^r = \int_{\underline{\theta}}^{\theta^*} (\theta(1-\tau) - \kappa p_g) d\theta = \frac{1}{2}(1-\tau) \frac{(\kappa + r(1-\tau)(1-\kappa))^2}{[\kappa(3+\tau) + 3r(1-\tau)(1-\kappa)]^2},$$

$$CS_g - CS_g^r = -\frac{\tau r(1-\kappa)(1-\tau)^2 [2\kappa(\tau+3) + r(1-\kappa)(6+\tau)(1-\tau)]}{2(3+\tau)^2 [\kappa(3+\tau) + 3r(1-\tau)(1-\kappa)]^2} < 0.$$

Assuming identical regulatory prices under the maximum price system and the reference price system, consumer surplus for brand-name users under the maximum price system can be written in terms of the regulatory parameter r as follows:

$$CS_b^m(r) = \frac{\left[\begin{array}{c} 4\kappa^2 \\ +r\kappa(2(-2\tau + \tau^2 + 5) - \kappa(3-\tau)^2) \\ +r^2(1-\tau)(1-\kappa)(6-\kappa(5-\tau)) \end{array} \right] \left[\begin{array}{c} 4\kappa^2(2-\tau) \\ +r\kappa(2(-6\tau + 3\tau^2 + 7) - \kappa(5-3\tau)(3-\tau)) \\ +r^2(1-\tau)(1-\kappa)(6-\kappa(7-3\tau)) \end{array} \right]}{8(\kappa + r(1-\kappa))^2 (\kappa(3+\tau) + 3r(1-\tau)(1-\kappa))^2}.$$

Taking identical regulatory prices as a basis of comparison, consumer surplus for brand-name users is higher under the maximum price system:

$$CS_b^m - CS_b^r |_{\hat{p}=R}$$

$$= \frac{r \left[\begin{array}{c} 4\kappa^3(2(-\tau^3 + 3\tau^2 + \tau + 1) - \kappa(1-\tau)^3) \\ +r\kappa^2(4(4\tau + 8\tau^2 - 8\tau^3 + 3\tau^4 + 5) - 4\kappa(-5\tau + 17\tau^2 - 15\tau^3 + 3\tau^4 + 8) + \kappa^2(11-3\tau)(1-\tau)^3) \\ +2r^2\kappa(1-\tau)(1-\kappa)(8(\tau+1)^2 - 2\kappa(-3\tau^3 + 7\tau^2 + \tau + 7) + \kappa^2(5-3\tau)(1-\tau)^2) \\ +r^3(1-\tau)^2(1-\kappa)^2(4(4\tau+1) - 8\kappa(\tau+1) + 3\kappa^2(1-\tau)^2) \end{array} \right]}{8(\kappa + r(1-\kappa))^2 (\kappa(3+\tau) + 3r(1-\tau)(1-\kappa))^2} > 0.$$

Assuming identical price reductions under the maximum price system and the reference price system, consumer surplus for brand-name users under the maximum price system can be written

in terms of the regulatory parameter r as follows:

$$CS_b^m(r) = \frac{\left[\begin{array}{l} 4\kappa^4(2-\tau) + 2\kappa^3r(17-15\tau+7\tau^2-\tau^3)(1-\kappa) \\ + \kappa^2r^2(53-68\tau+40\tau^2-12\tau^3+3\tau^4)(1-\kappa)^2 \\ + 12\kappa r^3(1-\tau)(3-2\tau+\tau^2)(1-\kappa)^3 + 9r^4(1-\kappa)^4(1-\tau)^2 \end{array} \right]}{2[\kappa+r(1-\kappa)]^2[\kappa(3+\tau)+3r(1-\tau)(1-\kappa)]^2}.$$

Taking identical price reductions as a basis of comparison, consumer surplus for brand-name users is higher under the maximum price system:

$$\begin{aligned} & CS_b^m - CS_b^r \Big|_{p_b^m=p_b^r} \\ &= \frac{r(1-\kappa) \left[\begin{array}{l} 2\kappa^3(1+\tau+3\tau^2-\tau^3) \\ + \kappa^2r(5+4\tau+8\tau^2-8\tau^3+3\tau^4)(1-\kappa) \\ + 4\kappa r^2(1-\tau)(\tau+1)^2(1-\kappa)^2 \\ + r^3(4\tau+1)(1-\tau)^2(1-\kappa)^3 \end{array} \right]}{2[\kappa+r(1-\kappa)]^2[\kappa(3+\tau)+3r(1-\tau)(1-\kappa)]^2} > 0. \end{aligned}$$

6.3 Competition in Pharmaceutical Markets

6.3.1 Brand-name Premium

If the market is not regulated, the brand-name price premium amounts to

$$\frac{p_b}{p_g} = \frac{2}{1-\tau}.$$

Under the maximum price system it is given as

$$\frac{p_b^m}{p_g^m} = \frac{2}{1-\tau}.$$

That is, under the maximum price system, price reductions for the brand-name drug are as high as for the generic drug.

Under the reference price system, the brand-name price premium amounts to

$$\frac{p_b^r}{p_g^r} = \frac{2}{1-\tau} \frac{\kappa+r(1-\tau)(1-\kappa)}{\kappa+r(1-\kappa)},$$

which is lower than under no regulation, as $\frac{\kappa+r(1-\tau)(1-\kappa)}{\kappa+r(1-\kappa)} < 1$. Reference pricing reduces the brand-name price to a larger extent than the generic price. This is due to higher price elasticity of demand for the brand-name price.

6.3.2 Generic Market Share

In the benchmark case of no regulation, the generic market share is given as

$$\frac{q_g}{Q} = \frac{1}{3}.$$

Under the maximum price, the generic market share amounts to

$$\frac{q_g^m}{Q^m} = \frac{1 - \frac{m(1+\tau)}{2}}{3 + \frac{m\tau(1+\tau)}{2}},$$

which is lower than under no regulation for $m > 0$. That is, by increasing the brand-name quantity and decreasing the generic quantity, the maximum price system decreases the generic market share and accordingly, it weakens generic competition.

Under the reference price system, the generic market share is given as

$$\frac{q_g^r}{Q^r} = \frac{1}{3},$$

which is as high as under no regulation. Thus, under the reference price system, brand-name and generic quantity increase by the same amount. Generic competition is not intensified under the reference price system.

Incentive for Product Differentiation

If the market is unregulated, brand-name and generic profit are given as

$$\Pi_b = \frac{4\tau}{\kappa(\tau+3)^2} \text{ and } \Pi_g = \frac{\tau(1-\tau)}{\kappa(\tau+3)^2}.$$

Brand-name profit increases with the degree of product differentiation

$$\frac{\partial \Pi_b}{\partial \tau} = \frac{4(3-\tau)}{\kappa(\tau+3)^3} > 0.$$

Hence, there is an incentive for the brand-name producer to raise his profit by raising the degree of product differentiation. Generic profit increases in τ , if $\tau < \frac{3}{7}$ and decreases otherwise:

$$\frac{\partial \Pi_g}{\partial \tau} = \frac{(3-7\tau)}{\kappa(\tau+3)^3} > 0 \text{ if } \tau < \frac{3}{7}.$$

This is, to some extent there is also incentive for the generic producer to raise τ . For a low degree of product differentiation, the positive strategic effect exceeds the negative direct effect. A certain degree of product differentiation allows the generic producer to attract additional consumers with a low valuation, but also forces it to lower his price.

Under the maximum price system, brand-name and generic profit are given as

$$\Pi_b^m = \frac{\tau(2-m(1+\tau)) \left[4 + m(\tau+1)^2 \right]}{2\kappa(\tau+3)^2} \text{ and } \Pi_g^m = \frac{\tau(1-\tau) [2-m(1+\tau)]^2}{4\kappa(\tau+3)^2}.$$

Both profits increase in τ for a low degree of regulation and decrease in τ for a high degree of regulation:

$$\frac{\partial \Pi_b^m}{\partial \tau} = \frac{\left[8(3-\tau) - 2m(3-\tau-9\tau^2-\tau^3) - m^2(11\tau+2\tau^2+3)(\tau+1)^2 \right]}{2\kappa(\tau+3)^3} < 0,$$

$$\text{if } m > m_b^* = \frac{\tau+9\tau^2+\tau^3+\tau\sqrt{36\tau+26\tau^2-4\tau^3+\tau^4+9}+3\sqrt{36\tau+26\tau^2-4\tau^3+\tau^4+9}-3}{(\tau+1)^2(11\tau+2\tau^2+3)}.$$

$$\frac{\partial \Pi_g^m}{\partial \tau} = \frac{\left[4(3-7\tau) - 4m(3-\tau-9\tau^2-\tau^3) + m^2(\tau+1)(2\tau-11\tau^2-2\tau^3+3) \right]}{4\kappa(\tau+3)^3} < 0$$

$$\text{if } m > m_g^* = \frac{6-14\tau}{2\tau-11\tau^2-2\tau^3+3}.$$

That is, for sufficiently strict regulation, there is no incentive to raise τ for both the brand-name producer and generic producer.

Under the reference price system, brand-name and generic profit are given as

$$\Pi_b^r = \frac{4\tau(\kappa+r(1-\tau)(1-\kappa))^2}{[\kappa+r(1-\kappa)][\kappa(3+\tau)+3r(1-\tau)(1-\kappa)]^2}$$

$$\text{and } \Pi_g^r = \frac{\tau(1-\tau)(\kappa+r(1-\tau)(1-\kappa))}{[\kappa(3+\tau)+3r(1-\tau)(1-\kappa)]^2}.$$

The relationship between profits and the degree of product differentiation is determined by the degree of regulation and the degree of product differentiation. The brand-name profit decreases in τ for a high degree of regulation and a high degree of product differentiation:

$$\frac{\partial \Pi_b^r}{\partial \tau} = \frac{4[\kappa+r(1-\tau)(1-\kappa)] \left[3r^2(1-\tau)^2(1-\kappa)^2 + \kappa^2(3-\tau) + \kappa r(6-7\tau-\tau^2)(1-\kappa) \right]}{[\kappa+r(1-\kappa)][\kappa(3+\tau)+3r(1-\tau)(1-\kappa)]^3} < 0,$$

$$\text{if } r > r_b^* = \frac{1}{6}\kappa \frac{7\tau+\tau^2-\tau\sqrt{26\tau+\tau^2-23}-6}{(1-\tau)^2(1-\kappa)} \wedge \tau > 8\sqrt{3}-13.$$

The generic profit decreases in τ for a high degree of regulation:

$$\frac{\partial \Pi_g^r}{\partial \tau} = \frac{\left[\kappa^2 (3 - 7\tau) + 3r^2 (1 - \tau)^3 (1 - \kappa)^2 \right]}{[\kappa (3 + \tau) + 3r (1 - \tau) (1 - \kappa)]^3} < 0,$$

$$\text{if } r > r_g^* = \kappa \frac{10\tau + \tau^2 + \tau \sqrt{20\tau + \tau^2 + 4} - 6}{6(1 - \tau)^2 (1 - \kappa)}.$$

The reference price system can only reduce the incentive to raise τ for the brand-name producer, if τ is already very high and if regulation is sufficiently strict. In this case, there is also no incentive to raise τ for the generic producer.

7 Welfare Analysis

Welfare under no regulation is given as:

$$\begin{aligned} W &= CS_b + CS_g + \Pi_b + \Pi_g - E \\ &= \frac{(9 + 5\tau - 2\tau^2)}{(\tau + 3)^2}. \end{aligned}$$

Welfare under the maximum price system is given as:

$$\begin{aligned} W^m &= CS_b^m + CS_g^m + \Pi_b^m + \Pi_g^m - E^m \\ &= \frac{\left[4(9 + 5\tau - 2\tau^2) + 4\tau m(\tau + 1)(3\tau + 1) - \tau m^2(3\tau + 1)(\tau + 1)^2 \right]}{8(\tau + 3)^2}. \end{aligned}$$

Welfare under the reference price system is given as:

$$\begin{aligned} W^r &= CS_b^r + CS_g^r + \Pi_b^r + \Pi_g^r - E^r \\ &= \frac{\left[\kappa^2 (5\tau - 2\tau^2 + 9) + r^2 (9 - \tau) (\tau - 1)^2 (\kappa - 1)^2 \right]}{2[\kappa (3 + \tau) + 3r (1 - \tau) (1 - \kappa)]^2}. \end{aligned}$$

Both regulatory instruments increase welfare:

$$W - W^m = -\frac{[4(9 - 5\tau) + \tau m(\tau + 1)(3\tau + 1)(4 - m - \tau m)]}{8(\tau + 3)^2} < 0,$$

$$W - W^r = -\frac{\left[\begin{aligned} &\kappa^2 (9 - 5\tau) (\tau + 3)^2 \\ &+ 2\kappa r (1 - \tau) (\tau + 3) (3 - \tau) (9 - 2\tau + \tau^2) (1 - \kappa) \\ &+ r^2 (81 - 45\tau + 21\tau^2 - \tau^3) (\tau - 1)^2 (\kappa - 1)^2 \end{aligned} \right]}{2(\tau + 3)^2 [\kappa (3 + \tau) + 3r (1 - \tau) (1 - \kappa)]^2} < 0$$

Assuming identical regulatory prices under the maximum price system and the reference price system, total welfare under the maximum price system can be written in terms of the regulatory parameter r as follows:

$$W^m(r) = \frac{\left[\begin{aligned} &4\kappa^4(-2\tau^2 + 5\tau + 9) + 4r\kappa^3(2(-\tau - 4\tau^2 + 3\tau^3 + 18) - 3\kappa(3 - \tau)(4 + \tau - \tau^2)) \\ &+ r^2\kappa^2(4(-3\tau^4 + 5\tau^3 - 3\tau^2 - 37\tau + 54) - 4\kappa(-3\tau^4 + 14\tau^3 - 11\tau^2 - 76\tau + 108)) \\ &\quad + r^2\kappa^2(\kappa^2(-3\tau^4 + 29\tau^3 - 37\tau^2 - 157\tau + 216)) \\ &+ 2r^3\kappa(1 - \tau)(1 - \kappa)(24(3 - \tau) - 2\kappa(-25\tau - 2\tau^2 + 3\tau^3 + 72) + \kappa^2(8 - 3\tau)(\tau + 3)(3 - \tau)) \\ &\quad + r^4(1 - \tau)^2(1 - \kappa)^2(36 - 72\kappa + \kappa^2(36 - \tau - 3\tau^2)) \end{aligned} \right]}{8(\kappa + r(1 - \kappa))^2(\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))^2}.$$

Taking identical regulatory prices as a basis of comparison, total welfare is higher under the maximum price system:

$$\begin{aligned} &W^m - W^r \Big|_{\widehat{p}=R} \\ &= r \frac{\left[\begin{aligned} &4\kappa^3\tau(2(\tau + 2\tau^2 + 1) - \kappa(1 - \tau)^2) \\ &\quad + r\kappa^2(\kappa^2\tau(11 - 3\tau)(1 - \tau)^2 - 12(-14\tau - \tau^2 + \tau^3 + 18)) \\ &- r\kappa^2(8\kappa(-16158\tau + 3791\tau^2 + 3859\tau^3 - 2702\tau^4 + 484\tau^5 + 224\tau^6 - 114\tau^7 + 18\tau^8 + 11610)) \\ &\quad + 2r^2\kappa\tau(1 - \tau)(1 - \kappa)(8 - 2\kappa(-2\tau + 3\tau^2 + 7) + \kappa^2(1 - \tau)(5 - 3\tau)) \\ &\quad + r^3\tau(1 - \kappa)^2(1 - \tau)^2(4 - 8\kappa + 3\kappa^2(1 - \tau)) \end{aligned} \right]}{8(\kappa + r(1 - \kappa))^2(\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))^2} > 0. \end{aligned}$$

Assuming identical price reductions under the maximum price system and the reference price system, total welfare under the maximum price system can be written in terms of the regulatory parameter r as follows:

$$W^m(r) = \frac{\left[\begin{aligned} &\kappa^4(9 + 5\tau - 2\tau^2) + 2\kappa^3r(18 - \tau - 4\tau^2 + 3\tau^3)(1 - \kappa) \\ &\quad + \kappa^2r^2(54 - 37\tau - 3\tau^2 + 5\tau^3 - 3\tau^4)(1 - \kappa)^2 \\ &+ 12\kappa r^3(1 - \kappa)^3(1 - \tau)(3 - \tau) + 9r^4(1 - \kappa)^4(1 - \tau)^2 \end{aligned} \right]}{2(\kappa + r(1 - \kappa))^2(\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))^2}.$$

Taking identical price reductions as a basis of comparison, total welfare is higher under the maximum price system:

$$\begin{aligned} &W^m - W^r \Big|_{p_b^m = p_b^r} \\ &= \frac{\tau r(1 - \kappa) \left[\begin{aligned} &2\kappa^3(1 + \tau + 2\tau^2) \\ &\quad + \kappa^2r(5 + 2\tau^2 - 3\tau^3)(1 - \kappa) \\ &\quad + 4\kappa r^2(1 - \kappa)^2(1 - \tau) + r^3(1 - \kappa)^3(1 - \tau)^2 \end{aligned} \right]}{2[\kappa + r(1 - \kappa)]^2[\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa)]^2} > 0. \end{aligned}$$

Total profits under the maximum price system:

$$\Pi_b^m + \Pi_g^m = \frac{\tau [4(5 - \tau) - m(\tau + 1) [8(1 - \tau) + m(\tau + 1)(3\tau + 1)]]}{4\kappa(\tau + 3)^2}$$

Total profits under the reference price system:

$$\Pi_b^r + \Pi_g^r = \frac{\tau [\kappa + r(1 - \tau)(1 - \kappa)] [\kappa(5 - \tau) + 5r(1 - \tau)(1 - \kappa)]}{[\kappa + r(1 - \kappa)] [\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa)]^2}$$

Assuming identical regulatory prices under the maximum price system and the reference price system, total profits under the maximum price system under the maximum price system can be written in terms of the regulatory parameter r as follows:

$$\Pi_b^m(r) + \Pi_g^m(r) = \frac{\tau \begin{bmatrix} 2\kappa \\ +r(2(1 - \tau) - \kappa(3 - \tau)) \\ -r^2(1 - \tau)(1 - \kappa) \end{bmatrix} \begin{bmatrix} 2\kappa^2(5 - \tau) \\ -r\kappa(21\kappa + 12\tau - 6\tau^2 - 16\kappa\tau + 3\kappa\tau^2 - 22) \\ +r^2(\tau - 1)(\kappa - 1)(-11\kappa + 3\kappa\tau + 12) \end{bmatrix}}{4(\kappa + r(1 - \kappa))^2(\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))^2}$$

Taking identical price reductions as a basis of comparison, total profits are higher under the maximum price system.

$$\begin{aligned} & \Pi_b^m + \Pi_g^m - (\Pi_b^r + \Pi_g^r) |_{\hat{p}=R} \\ &= \frac{r\tau \begin{bmatrix} -4\kappa^2(3\kappa - 3\tau^2 + \kappa\tau^2 - 1) \\ +r\kappa(4(1 - \tau)(3\tau^2 + 2) + 4\kappa(7\tau - 7\tau^2 + 3\tau^3 - 11) + \kappa^2(-3\tau^3 + 9\tau^2 - 25\tau + 35)) \\ +2r^2(\tau - 1)(\kappa - 1)(-20\kappa - 2\tau + 17\kappa^2 + 3\kappa^2\tau^2 + 6\kappa\tau - 6\kappa\tau^2 - 8\kappa^2\tau + 2) \\ +r^3(\tau - 1)^2(\kappa - 1)^2(11\kappa - 3\kappa\tau - 12) \end{bmatrix}}{4(\kappa + r(1 - \kappa))^2(\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))^2} > 0 \end{aligned}$$

Assuming identical price reductions under the maximum price system and the reference price system, total profits under the maximum price system under the maximum price system can be written in terms of the regulatory parameter r as follows:

$$\Pi_b^m(r) + \Pi_g^m(r) = \frac{\tau(\kappa + r(1 - \tau)(1 - \kappa)) \begin{bmatrix} \kappa^2(5 - \tau) + \kappa r(11 - 6\tau + 3\tau^2)(1 - \kappa) \\ +6r^2(1 - \kappa)^2(1 - \tau) \end{bmatrix}}{(\kappa + r(1 - \kappa))^2(\kappa(3 + \tau) + 3r(1 - \tau)(1 - \kappa))^2}$$

Taking identical price reductions as a basis of comparison, total profits are higher under the maximum price system.

$$\begin{aligned}
& \Pi_b^m + \Pi_g^m - (\Pi_b^r + \Pi_g^r) \Big|_{p_b^m = p_b^r} \\
= & \frac{\tau r (1 - \kappa) (\kappa + r (1 - \tau) (1 - \kappa)) (\kappa + r (1 - \tau) (1 - \kappa) + 3\kappa\tau^2)}{(\kappa + r (1 - \kappa))^2 (\kappa (3 + \tau) + 3r (1 - \tau) (1 - \kappa))^2} > 0.
\end{aligned}$$