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CENTRE FOR HEALTH ECONOMICS

**EX POST VALUE REGULATION OF
PHARMACEUTICAL PRICES**

Hugh Gravelle

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Hugh Gravelle*

Abstract

The paper examines the welfare properties of an *ex post average value* regulation scheme in which a pharmaceutical firm's revenue varies with the social value of its product. The mechanism, which is a variant of that proposed by Loeb and Magat, leads to efficient investment in R&D, production, consumption and promotion under certain market and technological conditions. The mechanism's attractive simplicity is lost when account is taken of the rivalrous nature of R&D, of the excess costs of taxes needed to finance the mechanism and of the multinational character of most pharmaceutical firms.

Keywords: Regulation. Research and Development. Pharmaceuticals. Reimbursement.

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*National Primary Care Research Centre, Centre for Health Economics, University of York, Heslington, York, YO1 5DD, email: hg8@york.ac.uk. Support from the Department of Health to the NPCRDC is acknowledged. The views expressed are those of the author and not necessarily those of the Department of Health.

1 Introduction

Different countries have adopted a bewildering range of methods of regulating prices and profits in the pharmaceutical industry (Bloor, Maynard and Freemantle, 1996). In this chapter I examine the welfare properties of an *ex post* average value (EPAV) regulation scheme in which a pharmaceutical firm's revenue varies with the social value of its product.¹ The scheme, which is a variation on the mechanism proposed by Loeb and Magat (1979), leads to efficient investment, consumption, promotion and production under certain market and technological conditions. I investigate what adjustments are necessary when these conditions are not satisfied and whether the adjustments vitiate the chief advantage of the scheme: its simplicity and transparency.

Figure 1 illustrates the mechanism, as originally proposed by Loeb and Magat. A monopoly profit maximizing firm faces the demand curve D and has marginal cost curve MC . The firm has fixed costs so that its average cost curve AC lies above MC . If the firm is unregulated and cannot price discriminate it will set a profit maximizing price p^m , produce output x^m and earn profit equal to the area π . If the demand curve measures consumers marginal willingness to pay, the efficient outcome is at x^* where the sum of consumer surplus and firm profit, not just profit, is maximized.

FIGURE 1 ABOUT HERE

One remedy would be to nationalize or regulate the firm, instruct it to set price equal to marginal cost and fund the resulting loss out of taxation. Problems with these solutions include reduced incentives for cost minimization and the deadweight distortionary losses stemming from the increase in taxation to cover losses.

Loeb and Magat (1979) suggest that the firm's price should not be regulated but that it should be paid a tax-financed subsidy equal to the consumer surplus generated by its chosen price. The firm's revenue is then equal to the amount paid by consumers plus their consumer surplus: total willingness to pay. Hence the firm will choose its price to maximize willingness to pay less cost or, equivalently, consumer surplus plus profit, and it will price at marginal cost. Since the firm will be bearing all production costs it will have the right incentive to minimize costs at any level of output.

The difficulties with the Loeb-Magat scheme are that the regulator needs to know the demand curve, though not the cost function. The scheme still

¹Maurice Peston has done much work on the regulation of pricing and investment of public sector firms. He maintains a current interest in the economics of the pharmaceutical industry through his role at the Office of Health Economics.

requires distorting tax finance and there are also distributional issues since the firm earns a reward equal to the social benefit from the industry. Loeb and Magat suggest that if the scheme is combined with a bidding competition in which firms offer payments for the right to run the industry under the scheme, the amount of subsidy which needs to be raised from distortionary taxation will be reduced, thereby also reducing distributional objections.

In the following sections we will investigate the scheme in the context of the pharmaceutical industry. The industry has a number of features which may affect the mechanism

- the industry is R&D intensive, so that we need to examine incentives for investment in research and development of new products
- the industry is also promotion intensive, so that we need to consider the impact of any scheme on the amount and type of information provided by firms to patients and doctors
- demand curves may not reflect the social benefits from the product because doctors may not be perfect agents for their patients or because patients with public or private health care insurance may not face the full price of the product
- firms are multinational: they produce and sell in more than one country

An alternative approach is to model the information asymmetry as less extreme and to investigate regulatory schemes based on the revelation principle which induce the firm to provide the regulator with its private information. Such schemes are usually complicated and assume sophisticated regulators who, in effect, have very precise information about their ignorance (Laffont and Tirole 1993). As we will see the main information problems in the regulation of the pharmaceutical industry arise from uncertainty about the benefits from new drugs and it is not obvious that information about these aspects are asymmetrically distributed. At the very least it seems of interest to consider whether there are simple schemes which can induce efficient investment.

2 The EPAV rule

2.1 Efficiency conditions

Pharmaceutical price regulation schemes vary, depending on the objectives of the regulator, the set of policy instruments and information available to

s	Payoff relevant state of the world defined by social value of drug
x_s	Quantity of drug consumed
α_s	Advertising by firm
$B_s(x_s, \alpha_s)$	Social benefit of drug in £
$B_{sx}(x_s, \alpha_s)$	Marginal social benefit of consumption
p_s	Price charged for consumers
$U_s(x_s, \alpha_s)$	Willingness to pay of consumers' agents
$c_s(x_s)$	Production cost of drug
$D_s(p_s, \alpha_s)$	Demand for drug
$c'_s > 0$	Marginal production cost
$v_s(x_s) = B_s - c_s$	Social value of drug in state s
r_s	Price paid to firm in state s
$R_s + R_0 = r_s x_s + R_0$	Reimbursement paid to firm
I	Investment in R&D by firm
$\pi_s = r_s x_s - c_s(x_s) + R_0$	Firm profit in state s
$f_s(I)$	Probability of state s
$V = E v_s - I$	Expected social value of R&D investment
$\Pi = E \pi_s - I$	Expected profit from R&D investment
h	Welfare weight on firm profit
λ	Marginal deadweight loss from taxation

Table 1: Notation

her and on the specification of demand, technology and uncertainty. We first consider a regulator whose objective is the maximization of the usual simple social welfare function: the unweighted sum of the expected surpluses accruing to individuals in the society in their role as consumers, taxpayers and owners of firms. Distributional and other objectives are introduced in Section 3.3

Optimal regulation of a pharmaceutical firm requires optimal investment by the firm, optimal consumption of whatever drug results from the investment, optimal (least cost) cost production and optimal provision of information to patients and their doctors. For the moment we ignore information provision and consider a firm which can invest in R&D which may result in a new chemical entity (NCE) which may have therapeutic value.

The therapeutic value of the drug $B_s(x_s)$ depends on the amount consumed x_s . The benefit function B_s may vary across states of the world s because of variations in its intrinsic qualities (proportion of cases of disease cured), the incidence of the condition treated and the value of health improvements. The state of the world is defined solely by reference to the

therapeutic value function.

The firm makes an investment I in R&D and the probability of state s occurring is $f_s(I)$ which varies with the amount of investment. We assume that R&D is productive in the sense that increases in I increase the expected value of the NCE which results but at a decreasing rate:

$$\sum_s f'_s(I) B_s(x) > 0; \quad \sum_s f''_s(I) B_s(x) < 0$$

Demand for the drug results from decisions by patients and doctors. The relationship between patients and doctors is one of imperfect agency (Arrow 1963) and there is no reason to suppose that consumption will be efficient. We need not specify this decision making process closely but assume that demand varies with the price charged to consumers p_s : $x_s = D_s(p_s)$, $D_{sp} < 0$.

The firm's *ex post* profit in state s , gross of its R&D expenditure, is

$$\pi_s = r_s D_s - c_s(D_s) + R_0 = R_s - c_s(x_s) + R_0 \quad (1)$$

where $c_s(x_s)$ is the firm's production cost, r_s the price it receives for its product and R_0 a lump sum payment which does not vary with the state of the world. R_s is the non-lump sum payment to the firm which may vary with the state of the world and its actions.

The *ex post* welfare function of the regulator in state s is an unweighted sum of the therapeutic benefits to consumers less the price they pay, the budget surplus accruing to taxpayers and the profit of firms. Once a drug has been invented its social value is the difference between its therapeutic value and the cost of production.

$$v_s(x_s) = B_s - c_s \quad (2)$$

The *ex ante* social welfare function is expected social value net of investment costs:

$$V = \sum_s v_s(x_s) f_s(I) - I \quad (3)$$

The first best choices of investment and consumption are defined by

$$V_I = \sum_s v_s(x_s) f'_s(I) - 1 = 0 \quad (4)$$

$$v_{sx}(x_s) = B_{sx}(x_s) - c_{sx}(x_s) = 0 \quad (5)$$

Note the interdependence of the consumption and investment decisions: the value of additional investment depends on the level of consumption in each state.

2.2 The EPAV rule

Assume an NHS type of institutional framework where the firm provides the drug to consumers and is then reimbursed by the state. Any payment by consumers is made to the state. If the marginal reward to the firm from any decision is equal to the marginal social value of the decision the firm will be induced to act efficiently. This can be achieved by choosing R_s so that the state contingent element of the firm's profit is equal to the social value v_s of its activities: $\pi_s - R_0 = v_s$. Hence if the regulator sets the state contingent revenue so that

$$R_s = B_s(x_s) \quad (6)$$

or equivalently reimburses the firm at the price

$$r_s(x_s) = \frac{B_s(x_s)}{x_s} \quad (7)$$

its profit in state s is

$$\pi_s = R_s + R_0 - c_s(x_s) = B_s(x_s) - c_s(x_s) = v_s(x_s) + R_0$$

and the firm has the incentive to take socially optimal decisions on investment. Since it bears all its production costs it will also have the incentive to produce its output at least cost.

If the firm has the option of not investing, the lump sum payment R_0 , which does not vary with the success of its R&D or any of its decisions, is constrained by the participation constraint that it must make a non-negative profit: $R_0 \geq I - \sum f_s(R_s - c_s)$. Since R_0 does not appear directly in the welfare function (3) and does not affect any of the firm's decisions the participation constraint will not be binding. We ignore the lump sum component of the regulation scheme until section 3.3

Efficient consumption is achieved by setting the price in each state so that

$$B_{sx}(D_s(p_s)) = c_{sx}(D_s(p_s)) \quad (8)$$

In general this will not imply that the price paid by patients is equal to marginal cost because the marginal social benefit from the drug need not be equal to the marginal private benefit.

FIGURE 2 ABOUT HERE

Figure 2 illustrates a case in which the marginal social benefit from the drug B_{sx} exceeds the marginal private benefit which is shown by the height of the demand curve D_s . The optimal consumer price is p_s^* which is less

than marginal cost. The curve B_s/x_s plots the *ex post* average value and the optimal reimbursement price is r_s^* . The efficient per unit reimbursement paid to the firm for any drug is equal to the actual per unit therapeutic benefit its investment creates.

The optimal reimbursement rate is a declining function of consumption but always exceeds marginal therapeutic value since $B_{sx} < B_s/x_s$. When the optimal consumer price defined by (8) is set, we see that the price paid to the firm exceeds its marginal cost of production. Even when the level of consumption is not efficient the EPAV rule provides the correct incentives investment for the firm because it is paid the actual therapeutic value of whatever drug results from its R&D.

If the firm charged consumers directly for the drug, so that it could control consumption via the price, EPAV would also lead it to choose the efficient price. The firm would collect the revenue from consumers and then receive a top up payment from the regulator such that its total state contingent revenue was $R_s = B_s$. Its profit is

$$B_s(D_s(p_s)) - c_s(D_s(p_s))$$

which is maximized by choice of p_s when

$$[B_{sx}(D_s(p_s)) - c_{sx}(D_s(p_s))] D_{sp}(p_s) = 0$$

so that the firm is led to set the optimal price satisfying (5) or (8) since $D_{sp} < 0$.

2.3 Incentives for promotion

The firm may be able to affect the sales of its product by promotional activities. When the firm's promotional activities enhance the benefits from the drug (advertising is informative) we have $B_s = B_s(x_s, \alpha_s)$, $B_{s\alpha} > 0$ where α_s is the firm's expenditure on promotion in state s . The value of the drug in state s is now

$$v_s(x_s, \alpha_s) = B_s(x_s, \alpha_s) - c_s(x_s) - \alpha_s \quad (9)$$

and the efficient first best level of promotion α_s satisfies

$$B_{s\alpha} - 1 \leq 0, \quad \alpha_s \geq 0 \quad (10)$$

with complementary slackness. Consumption of the drug now also depends on promotion as well as on the price charged to consumers: $D_s(p_s, \alpha_s)$. Increases in promotion increase consumption ($D_{s\alpha} > 0$).

The EPAV reimbursement rule (7) ensures that the firm has efficient incentives to engage in informative promotion since under the rule its profit is equal to the social value of its product and it bears all the promotion expenses:

$$\pi_s = r_s D_s(p_s, \alpha_s) - c(D_s(p_s, \alpha_s)) - \alpha_s = B_s(x_s, \alpha_s) - c(D_s(p_s, \alpha_s) - \alpha_s) \quad (11)$$

The firm will choose α_s to satisfy

$$(B_{sx} - c_{sx})D_{s\alpha} + B_{s\alpha} - 1 \leq 0, \quad \alpha_s \geq 0 \quad (12)$$

with complementary slackness, so that if consumption is efficient and satisfies (5) the firm's choice of α_s will satisfy the first best condition (10). If consumption is inefficient ($B_{sx} \neq c_{sx}$) the firm's choice of advertising is second best efficient: it will take account both of the direct benefit from better information ($B_{s\alpha}$) and the indirect benefit from increasing or reducing consumption if it is too low ($B_{sx} > c_{sx}$) or too high ($B_{sx} < c_{sx}$).

Even when the firm could indulge in distorting or persuasive promotion which has no social value ($B_{s\alpha} = 0$) but does increase demand ($D_{s\alpha} > 0$) EPAV will still provide the firm with the right signals. The firm will only wish to indulge in persuasive advertising if consumption less is than the first best level. It is led to choose both the correct level and type of advertising.

It is essential for the above arguments that the reimbursement price r_s is equal to *actual* average therapeutic value, rather than to some fixed value. For example, even if the regulator could successfully forecast the output level and promotion activity which would result from a fixed average value price and set this price to equal the actual social value, the firm would not respond efficiently. To see this suppose that advertising is only informative and that there are no externalities in consumption so that the demand and marginal social benefit curves coincide. Let the regulator fix a reimbursement rate $r_s = r_s^0$ which does not vary with the quantity consumed. The firm's profit in state s is

$$r_s^0 D_s(p_s, \alpha_s) - c(D_s(p_s, \alpha_s)) - \alpha_s \quad (13)$$

and it chooses its promotion expenditure $\hat{\alpha}_s$ to satisfy

$$(r_s^0 - c_{sx})D_{s\alpha} - 1 = 0 \quad (14)$$

where $D_{s\alpha} = -B_{sx\alpha}/B_{sxx}$. Even when the regulator correctly forecasts the firm's promotional activity and sets $r_s^0 = B_s(x_s(p_s, \hat{\alpha}_s))/(x_s(p_s, \hat{\alpha}_s))$ the firm will not have the correct incentives since its marginal revenue from additional advertising is

$$\left(\frac{B_s}{x_s} - c_{sx}\right) \frac{-B_{sx\alpha}}{B_{sxx}} \neq B_{s\alpha} \quad (15)$$

2.4 Proportional value scheme

The firm would also choose an efficient price and promotion under a scheme in which its profit in a state was a fraction of the social value: $\pi_s = kv_s, k > 0$. This would imply

$$\hat{R}_s = kB_s + (1 - k)c_s \quad (16)$$

so the firm received a weighted average of the therapeutic value and its costs. The proportional scheme has the appeal that when $k < 1$ the total payment to the firm is reduced since $kB_s + (1 - k)c_s < B_s$ and the burden on taxpayers is reduced. The proportional scheme has greater information requirements than EPAV but its most obvious drawback is that it does not provide the correct incentives for R&D or for cost reducing effort. Since the firm only gets a proportion of the social value of its invention it will be led to underinvest. Similarly it gets only a fraction k of any cost reductions it will not minimize production costs if this requires unobservable effort.

2.5 Several time periods.

The extension to many time periods is straightforward. The expected welfare function is a suitably discounted sum of costs and benefits and the firm's maximand is discounted expected profit. However, if its discount factor differs from the social discount factor the state contingent transfer must be adjusted to ensure that the firm's discounted profit in each period equalled the discounted social value of the drug. Efficient investment could still be achieved but the reimbursement rule would be more complicated and would require additional information.

For example, if the firm's constant one period ahead discount factor δ_f is proportional to the constant one period ahead social discount factor ($\delta_f = k\delta$) then the reimbursement in period t if state s occurs is $R_{st} = k^{-t}(B_{st} - (1 - k^t)c_{st})$.

2.6 Successive innovations

The value of the drug B_s should be calculated as the additional value of the drug over the next best product currently available in each period. When a new drug is introduced existing products for which it is a substitute will find their total and marginal benefit functions shifted downward. They will suffer both a loss in sales and a reduction in their reimbursement rates. They will however take this possibility into account when making their investment decisions and because the EPAV scheme equates revenue to social benefit of their product their investment decision will be socially optimal.

2.7 Information requirements.

Under EPAV the regulator must be able to estimate the benefit function in each state. This need only be done *ex post* at the end of each period: it is not necessary for the regulator to attempt to estimate *ex ante* the benefits from a drug in all future periods and states. The firm does have to estimate the benefits and costs in all future periods and states when taking its investment decision. Since this is precisely what is required for socially efficient investment, incentives for making good forecasts are correctly aligned.

When the setting of the consumer price is delegated to the firm the regulator does not need to know the firm's marginal cost. If for some reason the regulator wished to set the consumer price she could rely on the firm to truthfully report its marginal cost. The firm would realise that its report would affect the price set and therefore consumption. It would be motivated to offer a correct report because v_s is maximized when price is equal to marginal cost and its profit is increasing in v_s .

Even *ex post* the regulator's information requirements are not trivial but her task is made easier by having to make the estimates after consumption of the drug is known when they can be based on experience. The regulator does not need to know the firm's R&D technology, its production technology, or its level of investment.

Kremer (1996) has suggested a scheme which is very similar to EPAV. In his mechanism a firm which has discovered and patented a new product would be bought out of the patent by the government which could then either produce and sell the good at marginal cost or make the new technology available to any firm without charge. The price paid for the patent would be equal to the full social benefit of the good when consumed at a price equal to marginal cost. Even though Kremer suggests an ingenious auction mechanism to induce correct valuation of the patent to the firm (the stream of profits it would generate), the regulator would still need to know the benefit function in order to pay the firm the full social value of its invention.

3 Difficulties with the EPAV scheme

3.1 Multiple firms: R&D as rent seeking

The analysis so far has assumed that there is only one firm engaged in investment in R&D. But no set of property rights prevents firms from fishing in the pool of potential innovations. Exclusive rights are created by patents but these protect actual discoveries and do not limit access to the common pool of potential discoveries. With more than one firm the free access nature

of R&D activity means that investment by firms may be inefficient even if the successful firm is paid the therapeutic value B_s of its discovery.

Suppose that there are only two states: either the drug is discovered or it is not. Consider a two firm example in which only one firm will discover the cure for some disease and the probability of the cure being discovered is $f(I_1, I_2)$, $\partial f / \partial I_i > 0$. Assume that the probability that firm i makes the discovery, given that one is made, is $w_i = I_i / I$ where $I = I_1 + I_2$. The firm's expected profit (gross of investment) is $\pi^i = w_i f[R - c(x)]$ and it chooses its level of investment to satisfy (assuming it takes the other firm's investment as given)

$$\left[\frac{\partial w_i}{\partial I_i} f + w_i \frac{\partial f}{\partial I_i} \right] [R - c(x)] - 1 = 0 \quad (17)$$

The welfare function is now $f(B - c) - I_1 - I_2$ so that the condition for socially optimal investment by firm i is

$$\frac{\partial f}{\partial I_i} [B(x) - c(x)] - 1 = 0 \quad (18)$$

Setting $R = B$ will only lead to efficient investment by both firms when $\partial f / \partial I_1 = \partial f / \partial I_2 = f(I_1, I_2) / I$. There is no reason to suppose that the R&D technology would have such a special form.

The optimal reimbursement rate paid to firm i if it is successful is

$$R = \frac{[B(x) - c(x)]}{w_i} + c(x) > B(x) \quad (19)$$

The scheme induces the firm to invest efficiently. Its gross profit is $(B - c)/w$ so that it will choose an efficient price and promotion level. However it will not be led to choose an efficient level of cost reducing effort since it gets $\text{£}1/w_i > 1$ for every $\text{£}1$ reduction in cost: it will devote too much effort to cost reduction.

The regulator requires information about costs and firms' beliefs $w_i(I_1, I_2)$ about their chances of winning the R&D race. Note further that $R > B$. Thus consumers and taxpayers have a negative combined surplus from the optimal scheme if the lump sum component R_0 is zero. We return to this issue in section 3.3.

3.2 Complementary products

Some products are therapeutically complementary: a cocktail combining them may be more valuable than separate consumption. Take a very simple case in which two firms are investing in R&D and each may discover different

drugs with $f^i, i = 1, 2$. The event that a firm is successful is independent of the event that the other firm is successful. Assume that only the state in which both drugs are discovered is valuable: the drugs are useless if only one of them is used. The value of the drugs if both are invented is

$$B(z) - c_1(x_1) - c_2(x_s)$$

where $z = \min(x_1, x_2)$ because the drugs must be used in fixed proportions. The welfare function is $f^1 f^2 (B - c_1 - c_2) - I_1 - I_2$.

If each firm faces the reimbursement scheme

$$R^i(x_1, x_2) = B(z) - c_j(x_j) < B(z) \quad (20)$$

it receives the social value of the drug cocktail and is motivated to invest the efficient amount. Its expected profit is $f^1 f^2 (B_z - c_1 - c_2) - I_i$ and it chooses its investment to satisfy the efficiency condition $f^j \partial f / I_i (B - c_1 - c_2) = 1$.

The rationale is similar to that for the accident tax proposed by Vickrey (1968): when two or more parties can each affect the probability of some event they can be guided to make socially optimal decisions by making *all* of them bear the costs or receive the benefits of that event.

This version of the scheme requires cost information. The combined surplus of the consumers and taxpayers when both drugs are discovered is negative. The total payment to the firms is

$$2B - c_1 - c_2$$

so that the sum of consumer and taxpayer surpluses is $-(B - c_1 - c_2) < 0$

3.3 Distributional concerns

The EPAV scheme creates the right incentives for the firm because it pays it the social value of its decisions, so that the firm's objectives are identical to the welfare function. However, the firm gets all the surplus and the combined surplus of consumers and taxpayers is zero. Indeed in the circumstances of the previous two subsections the combined surplus of consumers and taxpayers may be negative. One answer is to use the lump sum part of the EPAV scheme. As we noted above a lump sum payment R_0 made irrespective of the state of the world does not affect the firm's incentives but does transfer some of the surplus back to the taxpayers. Thus the firm in effect buys the right to undertake R&D from the regulator, bears all the cost and keeps all the benefit. This is just another example of the standard Principal-Agent result: when the agent is risk neutral a first best allocation can be achieved by making the agent buy the productive opportunity from the Principal

The difficulty with the solution is that the regulator needs to know whether the lump sum exceeds the firm's expected gains: the participation constraint on the firm must not be violated. But this requires the regulator to know the R&D technology and to be able to forecast therapeutic benefits and production costs.

It might be possible in some instances to let potential investors bid for the right to invest. This would redistribute the surplus without the need for the regulator to be as well informed as the firms. Such a scheme would work only if the R&D was directed at a particular outcome (cure for a specific condition) and if it was certain that the R&D of other firms, engaged in the hunt for drugs aimed at other conditions, would not produce a cure for the condition. In effect the regulator would be selling the exclusive right to explore a piece of intellectual territory for valuable products. Unlike, say selling the rights to explore for oil in particular areas, it is not easy to define the territory.

Distributional concerns presumably arise because not all parties count equally in the welfare function. It is better to address the issue directly by reformulating the welfare function explicitly so that the implications of alternative value judgements are clearly spelled out, rather than by *ad hoc* adjustments to regulatory schemes derived from a welfare function in which only the total surplus, and not its distribution, matters.

One way of capturing distributional concerns is to give different weights to the surpluses of consumers, taxpayers and firm owners. As an example suppose that the weight on the surplus of firm owners is h so that the welfare function is now

$$V^h = E[B_s - h(c_s + I) - (1 - h)(R_s + R_0)] \quad (21)$$

where R_0 is the lump sum component of the regulatory scheme. In earlier sections we have implicitly assumed that $h = 1$ so that we have effectively been able to ignore R_0 because it had no effect on behaviour and was a pure transfer.

The firm's expected profit is $\Pi = E(R_s - c_s - I + R_0)$. Since R_0 does not vary with the firm's behaviour it can be induced to invest optimally by choosing R_s so that

$$\begin{aligned} \frac{\partial V^h}{\partial I} &= \frac{\partial [B_s - h(c_s + I) - (1 - h)R_s]}{\partial I} \\ &= \frac{\partial \Pi}{\partial I} = \frac{\partial E[R_s - c_s - I]}{\partial I} \end{aligned} \quad (22)$$

Solving the equation, the optimal reimbursement is

$$R_s = \frac{B_s + (1 - h)(c_s + I)}{2 - h} \quad (23)$$

Gross profit in each state is

$$\frac{B_s - c_s + (1 - h)I}{2 - h} \quad (24)$$

so that the firm will want to maximize the difference between therapeutic benefit and cost in each state. However, its incentives for cost reducing effort are too great for efficiency.

Since the marginal social value of the lump sum component is

$$\frac{\partial V^h}{\partial R_0} = -(1 - h) < 0 \quad (25)$$

the regulator should reduce R_0 until the firm's participation constraint just binds.

If a zero weight is given to profit the reimbursement rate is

$$R_s = \frac{B_s + c_s + I}{2} \quad (26)$$

Some manipulations show that this expression is greater or less than B_s if and only if $B_s - c_s - I$ is negative or positive. Since the expected value of $B_s - c_s - I$ is positive, the implication of being concerned only with the welfare of consumers and taxpayers is that the expected value of the reimbursement is smaller than if the welfare of owners counted equally. However in some states a higher reimbursement rate is required.

Suppose that the regulator bargains with the firm in each state about the level of the payment and, as in the previous paragraph, is concerned only about therapeutic benefits to consumers and the payment made by taxpayers. If the parties cannot reach agreement the regulator has zero payoff and the firm must bear its investment cost. The Nash bargaining solution which maximizes $(B_s - R_s)(R_s - c_s - I)$ is just (26). Thus a process of bargaining in each state where the firm anticipates the outcome of the bargain correctly would lead to an level of investment by the firm which maximized the expected payoff to consumers and taxpayers. The level of investment also maximizes the total surplus in the economy even though it is chosen by the firm and is not controlled directly by the bargain made since the Nash bargain gives the firm an expected profit of $E(B_s - c_s - I)/2$

Compared with the case in which there are no distributional concerns the regulator's task is much more difficult: she requires information on the firm's

costs in each state and on its investment. The firm will now have an incentive to mislead the regulator because its reimbursement depends directly on costs and investment.

3.4 Multi-national firms, chauvinistic regulators and regulatory coordination.

The welfare function considered in the previous section is the difference between the expected value of the drug and the costs of production, promotion and R&D. It implicitly assumes that policy makers do not care about the nationality of the firm's owners or the consumers, or that they are all members of the same community. A more chauvinistic welfare function might attach lower weights to the profits accruing to foreign shareholders or the benefits accruing to foreign consumers. (See Peston, Katz and Gravelle (1976) for a discussion of the implications of domestic and foreign consumers for public sector pricing.)

Consider a firm which produces a drug consumed at home and abroad and which is partly owned by foreigners. Denote the benefits accruing to home patients by B_{1s} , the amounts consumed by home and foreign patients by x_{1s} , x_{2s} respectively, and the non-lump sum and lump sum reimbursements in country i by R_{is} and R_{i0} . The *ex ante* welfare function for the home country is

$$V_1 = E[B_{1s}(x_{1s}) - (1 - \theta)(R_{1s} + R_{10}) + \theta[R_{20} + R_{2s} - c_s(x_{1s}, x_{2s}) - I]] \quad (27)$$

where θ is the proportion of the firm's profit which accrues to domestic owners of the firm.

The firm's expected profit is

$$\Pi = E \left[\sum_i (R_{i0} + R_{is}) - c_s - I \right] \quad (28)$$

and in order for the derivatives of (28) and (27) to with respect to I to be equal we require the reimbursement on home sales should be

$$R_{1s} = \frac{B_{1s} + (1 - \theta)[c_s + I - R_{2s}]}{(2 - \theta)} \quad (29)$$

The lump sum component will be reduced until the firm's participation constraint binds since V_1 is decreasing in R_{10} . The regulatory scheme is similar to the case in which the welfare weight on the firm's surplus is less than on the surpluses of consumers and taxpayers. The reimbursement is increasing

in the proportion of the firm's profit accruing at home, production costs and the level of investment and falling in the level of foreign sales revenue. The regulator now needs substantially more information than in the case where a domestic firm sells solely to domestic patients.

Surprisingly, it is possible that the reimbursement rate could be larger or smaller than in the case where there are no foreign sales or foreign shareholders whose welfare is disregarded.

Suppose that the regulator in the other country had similarly chauvinistic objectives but took the home regulator's policies as given. At the regulatory Nash equilibrium $(R_{10}, R_{1s}, R_{20}, R_{2s})$ the firm would choose its investment to satisfy

$$\frac{\partial \Pi}{\partial I} = \frac{\partial V_1}{\partial I} = \frac{\partial V_2}{\partial I} = 0 \quad (30)$$

whereas total welfare in the two countries is maximized at

$$\frac{\partial \Pi}{\partial I} = \frac{\partial V_1}{\partial I} + \frac{\partial V_2}{\partial I} = 0. \quad (31)$$

The firm makes too small an investment in R&D and there are welfare gains from regulatory coordination which will increase with the number of countries in which the firm operates.

3.5 Distortionary taxation

What might be called the first law of public finance is that there is no such thing as a lump sum tax: all taxes or subsidies alter the marginal rewards to actions and thus cause efficiency losses. To examine the implications of the deadweight loss from taxation, consider an NHS like system in which revenue from consumers is paid to the government. We can write the welfare function as

$$V^\lambda = E[B_s - c_s - I - \lambda(R_0 + R_s - p_s x_s)] \quad (32)$$

where λ is the deadweight loss per £1 raised from taxation. The deadweight loss is assumed to be constant and independent of the value of the innovation. Since the regulatory scheme will make a small impact on net public sector revenues this seems reasonable.

The optimal price charged to consumers satisfies

$$\frac{\partial V^\lambda}{\partial p_s} = (B_{sx} - c_{sx})D_{sp} + \lambda(x_s + p_s D_{sp}) = 0 \quad (33)$$

Remembering that $B_{sx} = \gamma_s p_s$ because of imperfect agency we have

$$\frac{\gamma_s p_s - c_{sx}}{p_s} = -\lambda \left(1 + \frac{1}{e_s}\right) \quad (34)$$

where e_s is the elasticity of demand with respect to the consumer price. This is similar to the standard inverse elasticity rule except that price should be reduced if there are positive externalities in consumption ($\gamma_s > 1$).

We can induce optimal investment by the firm by choosing R_s so that the derivatives of V^λ and Π with respect to I are equal which implies

$$R_s = \frac{B_s + \lambda p_s x_s}{1 + \lambda} \quad (35)$$

This also induces efficient behaviour in each state by the firm since once again the firm bears the marginal social benefits and costs. Consumer expenditure $p_s x_s$ is less than total benefit B_s , which implies that $R_s < B_s$. Deadweight costs of taxation lead to a smaller level of state contingent reimbursement for the firm. The optimal level of R_s is decreasing in the marginal deadweight cost λ . The greater the social cost of taxation the smaller the amount paid to the firm out of taxation. Note also that since there is a deadweight loss from taxation the lump sum component of the scheme should also be as small as possible.

4 Conclusions

The main objection to the NPAV mechanism is its informational requirements: even in its simplest form the regulator needs to know the therapeutic value of the drug. Some tentative steps have been taken to incorporating this kind of information directly in pharmaceutical regulation schemes (Drummond et. al. 1993; Drummond, Jöhnson and Rutten 1996) but much more could be done. Without direct use of measures of therapeutic value firms will have only indirect and almost certainly inappropriate incentives. For example, in a market in which there is no regulation the signal of therapeutic value provided to the firm is its revenue. But this is not even a good measure of consumer willingness to pay, since it fails to capture consumer surplus. Imperfect agency will drive a further wedge between revenue and social value.

The difficulties of evaluating pharmaceutical innovations are clearly great but this information would be required for any mechanism which provides suitable rewards for innovation. For example, efficient direct regulation of, or subsidy to, investment in R&D requires not only information on therapeutic value but also information about the innovation technology.

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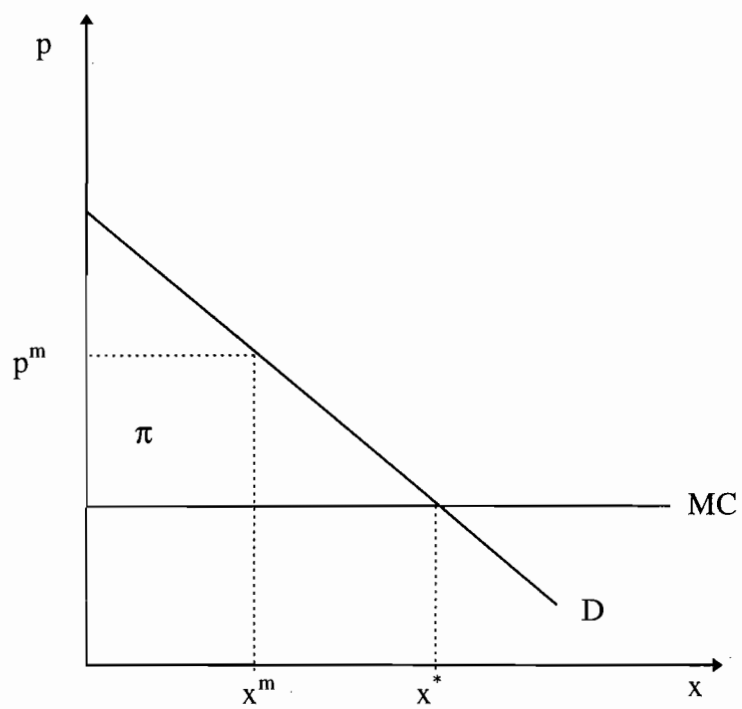


Figure 1

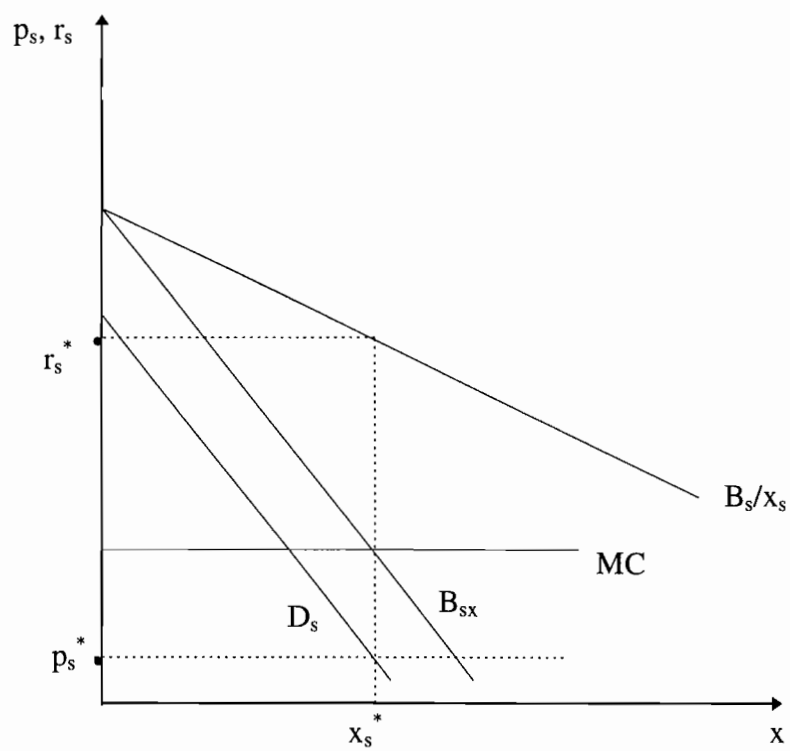


Figure 2. Ex post value reimbursement