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Barros, Pedro Pita

Universidade Nova de Lisboa

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Pedro Pita Barros*
Universidade Nova de Lisboa

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Abstract

The Janssen-Cilag proposal for a risk-sharing agreement regarding bortezomib received a welcome signal from NICE. The Office of Fair Trading report included risk-sharing agreements as an available tool for the National Health Service. Nonetheless, recent discussions have somewhat neglected the economic fundamentals underlying risk-sharing agreements.

We argue here that risk-sharing agreements, although attractive due to the principle of paying by results, also entail risks. Too many patients may be put under treatment even with a low success probability. Prices are likely to be adjusted upward, in anticipation of future risk-sharing agreements between the pharmaceutical company and the third-party payer. An available instrument is a verification cost per patient treated, which allows obtaining the first-best allocation of patients to the new treatment, under the risk sharing agreement. Overall, the welfare effects of risk-sharing agreements are ambiguous, and care must be taken with their use.

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Correspondence:
Pedro Pita Barros, Faculdade de Economia, Universidade Nova de Lisboa, Campus de Campolide, PT-1099-032 Lisboa, Portugal,
Email: ppbarros@fe.unl.pt, Ph: +351-213 801 600

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1 Introduction

Recently, Janssen-Cilag proposed an innovative scheme of risk-sharing with the English National Health Service (NHS) for bortezomib, which has received due attention from NICE - National Institute for Clinical Excellence. According to the Final Determination Appraisal from NICE,

> "the manufacturer rebates the full cost of bortezomib for people who, after a maximum of four cycles of treatment, have less than a 50% reduction in serum M-protein (that is, less than a partial response)" [NICE, 2007, p.1].

The risk-sharing idea is a novel approach, as no country used it in the early 1990s (Ballance *et al.*, 1992) and no mention is made in the survey by Scherer (2000). The Cooksey report strongly argues for a different approach in the way pharmaceutical prices are determined.[1] The OFT report (2007) suggests its use, though on a limited basis and with caution.[2] The changes proposed to the UK system of pharmaceutical pricing have led to an interesting and challenging discussion – see Claxton (2007), Towse (2007) and Thornton (2007). The risk-sharing agreement idea was used before in the UK, for the treatment of multiple sclerosis. This previous experience for beta interferon and glatiramer is discussed in Sudlow and Counsell (2003) and in OFT (2007, Annexe L, pp. 109 – 100).[3] The Janssen-Cilag case has also been discussed in the popular press (Pollack, 2007; Chapman, 2007). Carpenter (2007) hints that risk sharing may also hit the private health insurance companies in the United States. None of these discussions treat in detail

[1] Cooksey report (2006, p. 110): "A more productive approach, therefore, might be to look to combine some of the incentives involved in therapeutic pricing (and basing access to new treatments on cost-effectiveness) with reforms to expedite the Critical Path process of developing those treatments outlined above".

[2] OFT (2007, p. 91): "in a limited number of cases, a risk sharing approach could be adopted", and OFT (2007, p. 79): "risk sharing agreements would not be the norm."

[3] The earlier 1999 agreement betwen the North Staffordshire Health Authority and Pfizer (Parke-Davis at the time)for atorvastatin is also mentioned in OFT (2007).

the economics of risk-sharing agreements.

I argue here that too much optimism about risk-sharing agreements is probably misplaced. The main question to ask is whether this sort of risk sharing agreement is beneficial for the NHS, as the NICE claims it to be a "win-win" situation. At first sight, it seems to follow the principle of "paying for performance". However, the drawback may lie in the price, which may be higher than otherwise.

Moreover, relevant effects from an economic point of view may not end here. There are two other roles that may be performed by this risk-sharing agreement. The first is a pure signalling effect. Only firms holding a sufficiently high degree of confidence in their product will go for the system, as it is less costly for them than for the others. This will provide further information to the NHS and make it easier for the new drug to be adopted. This is a well-understood argument and it will not be addressed in depth here.

More interesting, in our view, is the alignment of incentives this system introduces to the NHS and to the pharmaceutical industry to assess the outcomes of treatments under the new drugs. Of course, since payment is conditional on outcomes, each will prefer an assessment different from that of the other party.[4] This may lead to a better use of pharmaceutical products, and consequently to lower health care spending overall. The NHS side, on the other hand, may use the new pharmaceutical product in patients in which a positive outcome has a very small probability, distorting the treatment decision towards the new technology. Therefore, a careful assessement of all indirect effects is called for.

The attractiveness of pharmaceutical risk-sharing can be, therefore, quite distinct from what one might expect at first sight.

[4]This element was present in the bortezomib case: the NHS claimed for a 50% reduction in serum M-protein, while Janssen-Cilag wanted a 25% reduction to be considered effective treatment.

The non-trivial element lies in the way therapeutical decisions may change under the risk-sharing arrangement, on the one hand, and on prices, on the other. Even in countries where prices are regulated (set administratively), firms are likely to use the argument that since the cost of the drugs is not paid out if no result is obtained, a higher price is needed to compensate for this risk. Whenever firms do not use, implicitly or explicitly, this argument, one may wonder whether or not the regulated price was set too high.

The paper is organized in the following way. Section 2 presents a simple model which lays down the basic economics of the risk-sharing agreement. Section 3 discusses the benefits and costs from risk-sharing agreements. Section 4 presents the social planner problem and the role of a verification cost per patient treated in achieving the first-best allocation of patients. Next, Section 5 discusses the role of detailing. Finally, Section 6 reports some final remarks.

2 The model

We consider a new treatmen, in our example a new pharmaceutical product, that yields a benefit $b > 0$ to the patient if successful. If the treatment is not successful, the patient is not harmed either. The treatment has effect on the patient with probability π.[5] Treatment probabilities differ across individuals in the population. We model population heterogeneity with regard to the probability of success treatment as being distributed in the interval [0, 1], according to a distribution function $F(\cdot)$, with density $f(\cdot)$. After a patient has been treated, the outcome can be verified at a cost c.

Medical doctors choose the range of patients to be treated. We assume that probability π can be observed by doctors prior to treatment. The new treatment

[5] An alternative modeling is to consider uncertain benefits, where b is random. This is formally equivalent to our approach.

is provided under patent protection and the firm providing it is a monopolist. The firm has the ability to set the price, p, of its product. Although it is true that in many countries pharmaceutical prices are regulated, the initial price of a new drug can often be influenced, if not completely determined, by firms. Moreover, patent protection has implicit the notion that R&D investments need to be recovered and price above marginal cost must exist for this purpose. Instead of modeling in detail how prices are formed, we take the simple assumption of monopoly pricing. As it will be apparent below, nothing essential depends on this assumption.

The timeline of decisions involves the firm deciding upon the price in the first stage, followed by doctors deciding on who receives the treatment. As usual, the model is solved by backward induction.

2.1 The decision of doctors

The decision of doctors consists of prescribing the new treatment to patients. Given our assumptions, it is easy to see that a continuous range of patients will be selected for the new treatment.

Whenever $b - p \geq 0$, it is worth treating the patient with probability 1 of success. Conversely, if $b < p$, using the new treatment yields a negative payoff to the institution paying for the treatment.[6] It is also clear that there is no benefit from treating patients with zero probability of success under the new treatment. Assuming $b - p > 0$, the optimal decision of treatment can be easily described by a cutoff value π^* such that above it, all patients with probability $\pi \geq \pi^*$ are subject to the new treatment, while for $\pi < \pi^*$ patients are diverted to alternative modes of treatment.

The utility for the doctors, under the current system of treatments being paid

[6]Social valuation will differ to the extent that p diverges from marginal cost of production.

whether successful or not, is given by:

$$U = \int_{\pi^*}^{1} f(\pi)(\pi b - p)d\pi \tag{1}$$

We consider doctors to be concerned with the patient's welfare and the cost of treatment provided. This assumption concentrates our focus on the implications of the risk-sharing agreement *per se* and not on the implications of physician's agency. The choice of π^* that maximizes this value is characterized by the following first-order condition:[7]

$$\frac{\partial U}{\partial \pi^*} = -f(\pi^*)(b\pi^* - p) = 0 \Leftrightarrow \pi^* = \frac{p}{b} \tag{2}$$

Let w be the marginal cost of production. A social planner would also maximize (1), with p replaced by w. As long as $p > w$, private decisions mean that fewer patients than is socially optimal are treated under the new treatment. This is the standard static monopoly distortion of the patent system.

2.2 The decision of firms

The decision variable for the firms is the price. The firm's valuation of sales is:

$$V = \int_{p/b}^{1} (p - w)f(\pi)d\pi \tag{3}$$

The problem faced by the firm is to maximize V with respect to p. The basic trade-off to the firm, in this context, is between a higher margin and a decrease in the number of patients treated. This is the traditional trade-off for a monopolist.

The first-order condition is given by

$$\frac{\partial V}{\partial p} = \int_{p/b}^{1} f(\pi)d\pi - \frac{p - w}{b} f(p/b) = 0 \tag{4}$$

[7]The second-order condition is also satisfied: $\partial^2 U/\partial {\pi^*}^2 = -f(\pi^*)b - (\pi^* b - p)\partial f/\partial \pi^*$.

where the first term collects the advantage of selling at a higher price while the second term reflects the cost of reduction in the number of patients treated. It is easy to see that $p > w$, so a margin above the socially optimal price exists and fewer patients will be treated than is socially optimal.

2.3 Risk sharing

We now introduce the proposal of risk-sharing between the pharmaceutical company and the NHS in our simple model. Risk-sharing means that a payment is due only if the treatment succeeds. Once the payment becomes conditional on outcomes, the issue of verifying the outcome arises, as both parties face opposite interests.

For each patient treated, the NHS has an interest in claiming that treatment did not work, in order to avoid payment, while the firm has an interest in claiming success even if the patient's condition did not improve. We assume that a cost c must be incurred in order to verify the outcome of treatment.[8] We also assume that this cost is borne by the NHS.[9]

The objective function of doctors is given by

$$U = \int_{\pi^*}^{1} f(\pi) \left[\pi(b-p) - c\right] d\pi \tag{5}$$

The main differences to the previous problem (1) lie in a) the price is paid only when treatment is successful; b) a cost c has to be paid per patient treated by the NHS.

It is easy to see that the optimal decision to doctors is to prescribe treatment

[8] Sudlow and Counsell (2003) provide a detailed description of and issues associated with this verification effort for the case of interferon beta and glatiramer for multiple scleroris.

[9] A more general approach would be to have that a fraction α of the cost is borne by the NHS and $(1-\alpha)$ by the firm. Since this alternative does not add any particular insight, we opt to use the simpler version.

whenever

$$\pi \geq \pi^* = \max\{1, \frac{c}{b-p}\} \tag{6}$$

For the remainder of the paper, we assume that c is sufficiently small relative to successful treatment gains such that $\pi^* < 1$. This also means that in the absence of a verification cost, all patients would be taken to treatment by the NHS as costs of unsuccessful treatments would fall on the pharmaceutical firm. Of course, this would not be socially optimal, as scarce resources would be spent on patients with a very small probability of actually benefiting from treatment. As the NHS doctors deciding on whether or not to put the patient under the new treatment takes prices as given, the over-treatment under uncostly verification holds for whatever price is established (as long as it remains below benefit b).

The value of sales to the firm is given by

$$\max_{\{p\}} V = \int_{\pi^*}^{1} (\pi p - w) f(\pi) d\pi, \pi^* = \frac{c}{b-p} \tag{7}$$

The corresponding first-order condition is given by:

$$\frac{\partial V}{\partial p} = \int_{\pi^*}^{1} \pi f(\pi) d\pi - \frac{c}{(b-p)^2} \left(\frac{c}{b-p} p - w \right) f\left(\frac{c}{b-p} \right) = 0 \tag{8}$$

Now, the impact of increasing a price is slightly more involved. On the one hand, the gains from raising the price are smaller, as the price is only received when the outcome of treatment is positive. On the other hand, the margin received is smaller in expected terms, meaning a lower cost of reducing demand by increasing the price. In addition, the decrease in patients treated would be higher the larger the price.

The comparison with equilibrium values without the risk-sharing agreement hinges upon the values of the verification cost c.[10]

A special case occurs for $c = 0$, in which outcome verification can be performed without costs. In this particular case, $\pi^* = 0$, and the equilibrium price is de-

[10] And also on how this cost is shared, α, if the more general approach is taken.

termined as the highest price acceptable to the NHS. Since doctors will prescribe treatment to all patients as long as $b - p > 0$, the optimal price to the pharmaceutical firm will be $p^* = b$.[11] Therefore, patients treated and costs will increase considerably under the risk-sharing agreement and with zero verification cost.

3 The advantage of the risk-sharing agreement

Take the price of the new treatment as fixed and a zero verification cost. Does the firm have any advantage from a risk-sharing agreement?

Let the profits without and with risk-sharing be denoted by V_0 and V_1, respectively, where:

$$V_0 = \int_{p/b}^{1} (p - w) f(\pi) d\pi, \qquad V_1 = \int_{0}^{1} (\pi p - w) f(\pi) d\pi \tag{9}$$

The change in profits is given by

$$\Delta V = V_1 - V_0 = \int_{0}^{p/b} (\pi p - w) f(\pi) d\pi - \int_{p/b}^{1} (1 - \pi) p f(\pi) d\pi \tag{10}$$

There is a gain from extending the number of patients that is treated but there is a cost of not receiving payments that would be received otherwise. This term may be positive or negative.

In terms of net benefits for the NHS, denote by U_0 and U_1 the net benefits without and with risk-sharing, respectively, given by:

$$U_0 = \int_{p/b}^{1} (\pi b - p) f(\pi) d\pi, \qquad U_1 = \int_{0}^{1} (b - p) \pi f(\pi) d\pi \tag{11}$$

[11] For this price, the doctors will actually be indifferent between prescribing the treatment, or not. The firm can avoid this by setting $p = b - \varepsilon$, where ε is the smallest unit of account possible. Since nothing essential is lost, we take $p^* = b$ and assume that under indifference doctors will always prescribe the new treatment.

The change in utility is

$$\Delta U = \int_0^{p/b} (b-p)\pi f(\pi)d\pi + \int_{p/b}^1 (1-\pi)pf(\pi)d\pi > 0 \tag{12}$$

In the above expression, the second term in the right-hand side is a net gain from not paying the treatment if the treatment does not benefit the patient. The first term, on the other hand, is the benefit from attempting to use the new technology in every patient that was not previously exposed to the treatment. Since the cost is paid only when the treatment has positive results, its impact is always positive.

Therefore, in the short run, holding prices fixed, risk-sharing with the provider of the new treatment is always beneficial to the NHS. In addition, if the agreement was put forward by the company, then it is licit to assume $\Delta V > 0$, so both sides benefit. Nonetheless, from a social point of view, too many patients are treated, as a negative social value for treatment exists for $\pi < w/b$.

Social welfare is defined as

$$W = \int_{\pi^*}^1 (\pi b - w)f(\pi)d\pi, \qquad \pi^* = p/b \tag{13}$$

when there is no risk-sharing agreement, and is given, under the risk-sharing agreement, by

$$W = \int_{\pi^*}^1 (\pi b - w - c)f(\pi)d\pi, \qquad \pi^* = \alpha c/(b-p) \tag{14}$$

When $c = 0$, the change in welfare from a movement from no-risk-sharing to risk-sharing is given by

$$\Delta W = \int_0^{p/b} (\pi b - w)f(\pi)d\pi \tag{15}$$

which can be higher or lower than zero. To see this, take $\pi = 0$. For this patient, the social value of prescribing the treatment is negative: the patient has zero probability of benefiting from the treatment and yet the treatment consumes resources.

Take now the patient with $\pi = p/b$. For this patient, the net social benefit is given by $p - w > 0$, meaning a gain is obtained from treating this patient under the risk-sharing agreement while (s)he was left out in the situation of no risk-sharing agreement. Since patients with both negative and positive social contributions will also be treated, the welfare effect can be either positive or negative.

This assessment is also valid even if the price of the pharmaceutical product is not kept constant across regimes. Over the medium and long run the pricing policy is also endogenous to the system. In this setting, it means firms, when introducing their new treatments into the market, will think also in terms of their pricing policy: a firm anticipating that it may want to later propose a risk-sharing agreement (or accept a proposal of the third-party payer) is likely to try to set a different price. We model this situation by assuming that the firm will have the freedom to set the price.

Even if both sides see an advantage to the risk-sharing agreement, social welfare, defined as surplus over marginal cost of production) may actually decrease (if there is a large number of patients with a low success probability). This can be easily seen from welfare change ΔW, given by $\Delta W = W_1 - W_0$ where

$$W_0 = \int_{p/b}^{1} (\pi b - w) f(\pi) d\pi, \qquad W_1 = \int_{0}^{1} (\pi b - w) f(\pi) d\pi \tag{16}$$

are the welfare measures without and with risk-sharing agreement, respectively. Adding the verification costs simply increases the range where social welfare decreases. Since price payments are a costless transfer between economic agents, and the distortion results from NHS doctors' decisions, the agreed price after introduction of the risk-sharing agreement is irrelevant to the welfare assessment.

4 The Social Planner's choice

We have seen above that no-cost verification leads to too many new treatments being given and to too high prices. Therefore, the existence of a verification cost per patient treated introduced some containment in the prescription of the new treatment. This can be beneficial as it will reduce the number of treatments under negative expected social value and drive down prices. We now go into more detail on the opportunities available to a benevolent social planner.

The unconstrained social optimum is given by

$$W = \int_{\pi^*}^{1} (\pi b - w - c) f(\pi) d\pi \tag{17}$$

and the social planner chooses $\pi^* = (w + c)/b$. However, the social planner seldom has a direct choice over who is treated. In a second-best world, the threshold π^* for treatment under the new technology is set by physicians. It can be influenced by the social planner through its choice of c (and p).

We can address the issue of first-best implementation in a second-best setting. This means that physicians decide on which patients are taken to the new treatment. Given that a verification cost τ is imposed, only patients with probability of treatment success higher than $\pi^* = \tau/(b - p)$ will receive the new treatment. The verification cost τ can be lower or higher than the true verification cost, as we allow the social planner to subsidize or to tax verification activities.

Under the fixed-prices regime, the first-best allocation of patients to the new treatment can be easily achieved by setting

$$\frac{\tau}{b - p} = \frac{w + c}{b} \tag{18}$$

or

$$\tau = (w + c)\frac{b - p}{b} \tag{19}$$

The value τ can be higher or lower than c.

However, this value may not be optimal in a second-best world as either money needs to be raised (if $c > \tau$) or financial resources become available to other objectives pursued by the social planner (if $\tau > c$). We are taking the creation of mechanisms to charge/pay the difference $(\tau - c)$ to be costless at the margin. Of course, a fixed cost of setting the system simply increases the range of situations where the risk-sharing agreement does not bring a higher social welfare. More relevant is whether a social cost of funds needs to be considered. However, its inclusion in the analysis needs to be done carefully, as the financial results of the NHS institution should also be weighted in the social welfare function. To avoid further cluttering the analysis, we consider the marginal costs of funds in the verification cost to equal marginal cost of funds to any NHS institution.[12]

Suppose now the pharmaceutical firm decides the price at which it sells the new product, after the social planner deciding on the level of the verification cost τ. Let $p = p(\tau), p'(\tau) < 0$ denote the optimal solution to the problem of the pharmaceutical firm.[13] That is:

$$p(\tau) = \arg\max_{\tilde{p}} V = \int_{\frac{\tau}{b-\tilde{p}}}^{1} (\pi\tilde{p} - w) f(\pi) d\pi \tag{20}$$

The social planner chooses τ in the following problem:

$$\max_{\tau} W = \int_{\frac{\tau}{b-p(\tau)}}^{1} (b\pi - w\tau)\, f(\pi) d\pi + \int_{\frac{\tau}{b-p(\tau)}}^{1} (\tau - c) f(\pi) d\pi \tag{21}$$

The corresponding first-order condition yields:

$$\frac{\partial W}{\partial \tau} = \left(\frac{b - p(\tau) + \tau p'(\tau)}{(b - p(\tau)^2} \right) \left(\frac{\tau}{b - p(\tau)} - w - c \right) f\left(\frac{\tau}{b - p(\tau)} \right) = 0 \tag{22}$$

So, either

$$\frac{\tau}{b - p(\tau)} = w + c \tag{23}$$

[12] This assumption matches similar ones in recent analysis, see Brekke *et al.* (2007), for example. It also has the advantage of not implying that authorities may want a verification cost as a way of obtaining funds to apply elsewhere.

[13] This is more clearly formalized in the appendix.

or

$$\frac{\tau}{b - p(\tau)} = -\frac{1}{p'(\tau)} \tag{24}$$

Under the technical conditions assumed, only the value resulting from the first expression satisfies the second-order condition for a maximum. This condition highlights that from a social planner point of view it is irrelevant whether the verification cost is set before or at the same time of price re-alignments by the pharmaceutical company.[14] Intuitively, this results from the fact that the social planner wants the new treatment to be given to patients as long as they have a positive expected net social value ($b\pi - w - c > 0$), taking the price paid by the drug to be a costless transfer between agents in the economy.

5 The role of detailing

For ease of exposition, let us assume once again that prices are fixed. However, the pharmaceutical company can undertake marketing and advertising campaigns, detailing activities, to lead physicians to use their product as the preferred treatment. Let η be the detailing effort. The valuation by the physician from providing the new treatment is now given by:

$$U_0 = \eta + \pi b - p \tag{25}$$

in the absence of a risk-sharing agreement, and it is

$$U_1 = \pi(b - p) + \eta \tag{26}$$

under the risk-sharing agreement. We assume that detailing effort has a cost given by $1/2\eta^2$ to the pharmaceutical company.

In the absence of risk-sharing, treatment using the new drug is prescribed whenever $\pi b - p + \eta > 0$. Thus, for $\pi > \pi^* = (p - \eta)/b$, the new treatment is given to the

[14] Technically, this results from $p'(\tau)$ being irrelevant to the optimal choice of τ.

patient.[15]

The pharmaceutical company chooses marketing effort η in order to maximize its profits, and in the absence of a risk-sharing agreement, it amounts to

$$\max_{\eta} V_0 = \int_{\frac{p-\eta}{b}}^{1} (p-w) f(\pi) d\pi - \frac{1}{2}\eta^2 \tag{27}$$

The optimal choice of detailing level balances the benefits of inducing higher adoption against the marginal cost of undertaking the effort. The associated first-order condition is given by

$$\frac{\partial V}{\partial \eta} = \frac{1}{b}(p-w) f\left(\frac{p-\eta}{b}\right) - \eta = 0 \tag{28}$$

In clear contrast, under the risk-sharing agreement everyone is treated. Therefore, the new drug does not require advertising or marketing effort to be widely accepted. The optimal value of detailing in this case is zero, as there is no marginal benefit from detailing but there is certainly a cost.

With a verification cost to the outcome of the treatment, a trade-off reappears. In the event of a risk-sharing agreement, it is no longer optimal to treat all patients, and with a positive verification cost of success, the number of patients treated with the new pharmaceutical product can increase or decrease. Following it, the level of marketing activities may decrease or increase. The intuition is relatively straightforward. When the verification cost c is very high, only a very low number of cases are treated, which increases the marginal value of inducing some further treatments. Since only patients with a high probability of success are included for treatment with the new drug, it is more likely that a payment is received by the pharmaceutical company, a feature that naturally increases the marginal value to detailing activities.

Thus, as long as verification costs are not too high, we should expect a decrease in detailing activities at the hospital by the pharmaceutical company.

[15] We implicitly assume $\eta < p$.

6 Final remarks

According to our analysis, there is more to be said about risk-sharing agreements between third-party payers, like the NHS, and pharmaceutical companies than has been recognized so far.

The Cooksey report, the OFT recommendation and the recent practice by NICE seem, at first glance, to be compelling as they follow from the principle of paying by results. Indeed, we were able to easily show that under fixed prices for pharmaceutical products: a) the NHS payments decrease, on average; b) profits of the pharmaceutical company may increase or decrease; and c) all patients will be treated with the new drug (as it has no financial costs in the event that the treatment does not succeed).

Underlying this result we have several assumptions. Some of them are innocuous. One is not. The implicit assumptions, which do not change the role of risk-sharing agreements, are "no-harm done" to patients if the treatment fails and availability of the old drug treatment (or any alternative treatment) in the event that the new pharmaceutical drug fails to treat the patient.

The assumption that has an important role on the desirability of risk-sharing agreements is that of fixed prices. Existing discussions assume drug prices to have already been set and to be fixed. However, this assumption is unlikely to hold. Either pharmaceutical firms have the freedom to set prices and will change them after the risk-sharing agreement, or if they anticipate entering some sort of outcome-related payment, they will fight for a different price to be set. In either case, prices of pharmaceutical products will not be the same with, or without, risk-sharing agreements.

Prices will be adjusted upward, to face the costs not covered by absence of payment in case of treatment failure. Also, pharmaceutical companies will face a less elastic

demand (and will look for higher prices).

On the NHS side, treatments are expanded to a larger set of patients, now including those cases which, in social valuation, are not worth treating under the new technology, in an ex-ante assessment.

However, since the decision maker at the hospital only pays the price after successful treatment, costs of providing treatment in the event of failure are ignored. Accordingly, too many treatments will be provided in the sense that patients that have a low probability of treatment success will also be included, although from a social point of view, it would be better to use an alternative treatment.

Depending on the magnitude of this latter effect, NHS costs may actually increase under the risk-sharing agreement.

The adjustment in prices therefore has the potential to undermine the advantages of the risk-sharing agreement.

There are two other relevant issues to discuss. The first one is observability of success from treatment with the new pharmaceutical product. The second issue is the role of detailing and product promotion by the pharmaceutical company.

The risk-sharing agreement introduces the need to verify treatment outcomes. Payers have an incentive to claim failure in order to avoid payment and firms have an interest to declare success in order to receive payments. Whenever there is a cost to ensure verification of treatment outcomes, assuming it is by the NHS, treatments will not be expanded as widely as in its absence. Of course, for sufficiently high verification costs, the risk-sharing regime will deliver lower social welfare than the no-risk-sharing regime. It is also the case that by imposing an appropriately defined verification cost on the NHS decision-maker, it is possible to achieve the first-best allocation of patients to the new treatment. Therefore, a payment per patient treated is advocated even under the risk-sharing agreement. This can

be met by verification cost, and may be higher or lower. A careful analysis is required on a case by case basis. The meed for outcomes verification, in the sense of acquiring evidence about need and value after coverage if granted, cannot be overemphasized. This issue also arises in schemes aimed at setting prices that will be later reviewed according to evidence.

On the second issue, detailing by the pharmaceutical company, the risk-sharing agreement reduces, in general, the incentive for detailing, as the risk-sharing agreement expands the range of patients the NHS decides to treat under the new technology. In this sense, it substitutes for detailing activities by pharmaceutical companies. However, if the verification cost is high and the number of patients treated actually decreases with the introduction of the risk-sharing agreement, then in such cases detailing effort may increase, to counteract a reduction of patients treated.

Overall, our results argue that the call for a wider use of risk-sharing agreements between the NHS and the pharmaceutical industry, which has been recently met by the NICE decision regarding bortezomib, needs to be assessed with care. Only under a restrictive set of assumptions is it welfare improving, with a crucial assumption being fixed prices. Fixed prices means here that pharmaceutical firms want to carry the same price on their product whether the risk-sharing agreement exists, or not. Nonetheless, using as a policy instrument a verification cost paid by the NHS institution, independent of realized outcomes, allows the first-best allocation of patients to the new treatment to be reached.

The main message can be conveyed in a simple statement: The policy of risk-sharing agreements is to be used with care, otherwise it can easily produce unexpected results, especially if price adjustments exist.

References

Ballance, R., J. Pogany and H. Forstner, 1992, The world's pharmaceutical industry: an international perspective on innovation, competition and policy, Edward Elgar and United Nations Industrial Development Organization.

Brekke, K., I. Konigbauer and O.R. Straume, 2007, Reference pricing of pharmaceuticals, Journal of Health Economics, 26(3): 613 – 642.

Carpenter, P., 2007, Medications in Texas may soon be given money-back guarantees, http://www.ezienarticles.com.

Chapman, S., 2007, Editorial - Outcome guarantees: putting your money where your mouth is, Prescribers, 18(17).

Claxton, K., 2007, OFT, VBP: QED?, Health Economics, 16(6): 545 – 558.

Cooksey, D., 2006, A review of UK health research funding, HMSO, London, UK.

OFT - Office of Fair Trading, 2007, The pharmaceutical price regulation scheme: an OFT market study, Office of Fair Trading, London.

NICE - National Institute for Clinical Excellence, 2007, Final Appraisal Determination - Bortezomib monotherapy for relapsed multiple myeloma.

Pollack, A., 2007, Pricing pills by the results, The New York Times, 14 July 2007.

Scherer, F.M., 2000, The pharmaceutical industry, chapter 25, pp. 1297 - 1338, in A.J. Culyer and J.P. Newhouse, editors, Handbook of Health Economics, North-Holland, 2000.

Sudlow, C. and C. Counsell, 2003, Problems with the UK Government's risk sharing scheme for assessing drugs for multiple sclerosis, British Medical Journal, 326: 383 – 392.

Towse, A., 2007, If it ain't broke, don't price fix it: the OFT and PPRS, Health Economics, 16(7): 653 – 665.

Thornton, S., 2007, Drug price reform in the UK: debunking the myths, Health Economics, 16(10): 981 – 992.

Appendix

The second-best solution

Suppose that the pharmaceutical firm decides the price at which it sells the new product. In a previous stage, the social planner was able to set the level of the verification cost. The problem of the pharmaceutical firm is given by:

$$\max_{p} V = \int_{\frac{\tau}{b-p}}^{1} (\pi p - w) f(\pi) d\pi \tag{29}$$

The solution to this decision problem is provided by the solution to the first-order condition:

$$\frac{\partial V}{\partial p} = -\frac{\tau}{(b-p)^2}\left(p\frac{\tau}{b-p} - w\right) f\left(\frac{\tau}{(b-p)^2}\right) + \int_{\frac{\tau}{b-p}}^{1} \pi f(\pi) d\pi = 0 \tag{30}$$

From this expression,

$$\begin{aligned}\frac{\partial^2 V}{\partial p \partial \tau} &= -\frac{1}{(b-p)^2}\left[\frac{2p\tau}{b-p} - w\right] f\left(\frac{\tau}{b-p}\right) - \frac{1}{(b-p)^2}\left(p\frac{\tau}{b-p} - w\right) \times \\ &\quad \times f'\left(\frac{\tau}{b-p}\right)\frac{1}{b-p} - \left(\frac{1}{b-p}\right)^2 f\left(\frac{\tau}{b-p}\right)\end{aligned} \tag{31}$$

If $f'(\cdot)$ is not sufficiently negative and $p\tau/(b-p) - w > 0$, the sign of $\partial^2 V/\partial p \partial \tau$ is negative. The second condition implies that the marginal patient has positive value for the pharmaceutical company. The negative sign of the overall expression implies that an increase in the verification cost reduces the price charged by the pharmaceutical company. The intuition runs as follows: by increasing the verification cost, the social planner leads the physician to increase the threshold of patients submitted to the new treatment. If the marginal patient is profitable to the pharmaceutical company, its optimal reaction is to decrease the price to induce a smaller increase in the marginal probability of treatment success that leads physicians to decide to use the new treatment. Now, from the first-order condition, it is easy to see that in equilibrium, it must be the case that $p\tau/(b-p) - w > 0$.