

Searching for approval: risk sharing as price discount?

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Abstract

We examine the effects of risk sharing pricing agreements for new drugs both on consumers' surplus and expected profit. We show that the presence of an uncertain listing process means that risk sharing produces two separate effects a price reduction as most of the literature has considered, but it will also influence the probability of listing. Expected prices are usually reduced by risk sharing agreements hence profit are decreasing. However, risk sharing may have an effect on the listing decision itself and for this reason the both ex ante expected profit and consumers surplus may increase after the introduction of these schemes.

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1 Introduction

One of the fundamental problems in the health care sector is that in most cases the technological process increases costs. For drugs, the increase in expenditure has generated a new interest in pricing policies: In public health care systems where about 3/4 of the cost of drugs is borne by the public sector this is a priority, but some form of regulation are presently discussed also by countries where health care expenditure mainly financed through private insurances. In public health care systems the forms are heterogeneous and include, for example, direct price regulation through a negotiation process ,indirect price regulation through limits on reimbursement under social insurance programmes ([Carone *et al.*, 2012]; [Panos *et al.*, 2010])

Even in the USA where prescription drug prices are largely unregulated, a form of bargaining exists between the insurance companies or HMO's (Health Maintenance Organisations) and the industry to have the new drugs reimbursed.

The aim of these regulatory mechanisms is to find an optimal trade-off between the need to incentivate R&D, to protect consumer and to promote value for money in the use of public funds. The latter aspect is particularly important: in health care the outcome of any treatment is uncertain and, to some extent, unverifiable because it depends on personal characteristics of each patient. For this reason the beneficial effects of the new drugs can be evaluated only in expected terms.

In order to improve value for money in health care, most national authorities have introduced restrictions on access or reimbursement to drugs.¹ The NHS in the UK has been one of the first health care systems to use them explicitly through the institution of NICE (National Institute of Clinical Excellence), but soon other countries have introduced similar systems². These systems have raised a very important debate on the effects of such mechanism on access and equity.³ Regulatory bodies across Europe are moving towards more complex schemes for drug pricing that can be generally described under the name of risk sharing agreements ([De Pourville, 2006]; [Cook *et al.*, 2008]; [Adamski *et al.*, 2010];[Antonanzas *et al.*, 2011];[Barros, 2011]), even though the evidence on their effectiveness in reducing expenditure and improve outcomes has still to be proved.

Risk sharing stems from the consideration that the price of the drug is often defined on its expected efficacy as derived from the randomised clinical trials carried out before the drug is approved. Once the drug has been introduced, almost any regulatory system foresees procedures to check the drug for possible side effects, while only few of them verify the real ex post value for money of the drug by imposing a form of penalty if the effectiveness falls short of the declared efficacy and/or the volume is greater than what agreed.

¹In this case, the number of patients eligible for a specific treatment is restricted to those that are expected to receive the higher benefit. For a review see [Claxton *et al.*, 2008] and [Appleby *et al.*, 2009].

²See [Neumann, 2005] for a review.

³See [Levaggi and Levaggi, 2011] and references therein.

Some forms of risk sharing agreements have been introduced in some countries (e.g. UK and Italy), where for some drugs the manufacturer has to rebate the full or the 50% of the treatment in case of failure.

While there may be difficulties in devising such schemes for every product, risk-sharing agreements may become an essential feature of the market in the future ([Cook *et al.*, 2008]).

In this paper we examine the effects of risk sharing both on consumers' surplus and expected profit. We show that the presence of an uncertain listing process means that risk sharing produces two separate effects that should take into account: the price regulation has a clear effect on profit and consumers surplus conditional on being listed and our results mostly confirm the results of the previous literature. Expected prices are usually lower than without risk sharing hence profit are decreasing. However, risk sharing may have an effect on the listing decision itself and for this reason the both ex ante expected profit and consumers surplus may increase after the introduction of these schemes. This effect mainly depends on the listing process each regulator decides to use.

2 Risk sharing agreements

The rapid increase in pharmaceutical expenditure and the need to control the health care budget has sparked renewed interest in pricing policies through the introduction of form of payment related to the real effectiveness of the drug. ([Claxton, 2007]) The latter pricing schemes go under the name of performance based contracts or risk sharing . In the pharmaceutical market risk sharing is said to occur when the risks involved (in this case the cost of a particular drug therapy) are shifted from one stakeholder to another, from the government to the industry and vice versa, in order to alleviate some of the concerns about uncertainty. Such risk may be related to the performances of the new drug or to the financial cost of provision. The latter aspect relates to the budget that should be set aside to list a new drug and the often observed problem to control the quantity of each drug sold after it has been listed ([Zaric and O'Brien, 2005]). Performance based contracts are increasingly popular in the general surge of interest in "value for money " in health care. [De Pourville, 2006] defines such agreements as "a contract between two parties who agree to engage in a transaction in which one party has sufficient confidence in its claims that it is ready to accept a reward or a penalty depending on the observed performance." which may be considered equivalent to the definition of [Towse and Garrison, 2010] of performance-based agreements "one between a payer and a pharmaceutical, device or diagnostic manufacturer where the price level and/or revenue received is related to the future performance of the product in either a research or a real-world environment".

[Lilico, 2003] show that if patients are risk averse and industries risk neutral, risk sharing agreements may be advantageous for both parties even if prices are increasing. The welfare improvement is positively related to the price of the drug, the disutility of the treatment and the severity of the disease. However,

on this point there is not agreement in the literature. [Barros, 2011] shows that these mechanisms may decrease welfare; [Towse and Garrison, 2010] argue that performance based schemes may be efficient only if a number of conditions are met. They relate to the cost of the contract in terms of evidences that must be collected for its application, with the use of the new information, with the writing of the contract and with the degree of risk aversion of payers and manufacturers and the transferability of information to one country to another.

In spite of this interest very little is known about the welfare implications of risk sharing and in this paper we want to partially fill the gap by studying this aspect.

3 The model

In this paper we study the effects of risk-sharing in markets for highly targeted new drugs. We can assume that ex ante the treatment is always appropriate and that the expected effectiveness of the drug does not depend on the number of patients to be treated.

We study the game between the industry and the regulator in setting the price of a new drug. The negotiation process is characterized by two elements: uncertainty on the effectiveness of the new drug and asymmetry of information. We assume that while the expected effectiveness of the drug can be verified by both parties through the results of the randomised clinical trials the industry has to produce to the regulator, the true, ex post effectiveness is not known when the price is set. Such uncertainty depends on several elements such as the role of compliance, the interactions with other drugs when patients have several pathologies, the appropriateness of physicians' prescription behaviour. The standard agreement between the industry and the regulator foresees a contract where the industry asks for a price based on the expected effectiveness; the regulator may accept such proposal and list the drug or it may deny approval. In our model we introduce a form of risk sharing of this nature: the industry proposes a price based on a level of effectiveness that may be equal to the expected effectiveness or it may be different; the regulator may accept this price and list the drug or refuse it. This decision depends on the cost effective is the new drug. Ex post, if the true effectiveness falls below the level the industry had promised at the time of listing a penalty (in the form of a rebate on the price) will have to be paid. The timing of the contract can be written as follows:

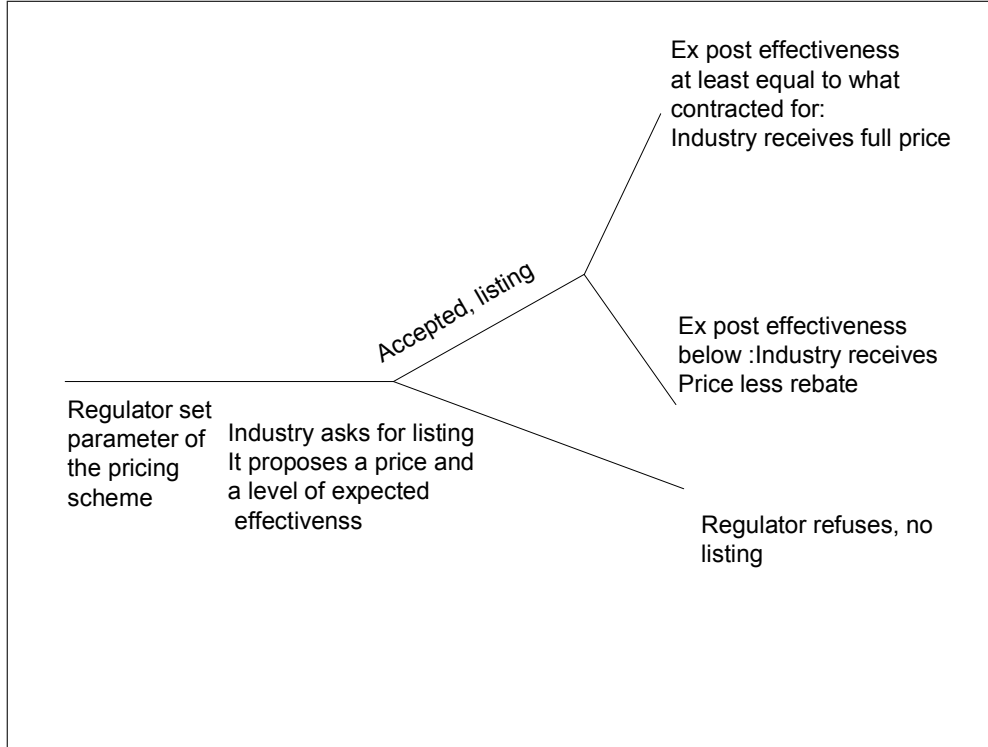


Figure one: The timing of the game

At the time of setting the price, the industry knows that its drug may be listed or not with a specific probability that depends on the level of cost effectiveness. The price scheme is already defined and foresees the payment of the full price only if a target level of effectiveness is reached ex post.

3.1 The environment

Let's consider a community that consists of a mass of individuals, normalised to one. Each individual has a fixed exogenous income M in the support $(0, Q)$ and an initial endowment H of health. Income is distributed according to a density function f and we denote by $Y = \int_0^Q Y f(Y) dY$ its average.

The stock of health H which may decrease to δH with probability v .

A new drug is about to be commercialised. Its effectiveness e may vary in the interval $(0, a)$ with $a \leq \delta$ according to a uniform probability distribution so that the expected effectiveness is $\frac{a}{2}H$. The price of the drug is equal to p and one unit is sufficient to restore health. Patients have access to the drug if it is listed and the cost is borne by the public sector through a with a proportional tax on income at rate t .

The cost effectiveness parameter of the new drug is defined by

$$c_E = \frac{p}{e}$$

We assume that the regulator defines a maximum (α) and minimum (β) level of willingness to pay for the drug. We argue that this scheme reflects the regulatory process in most systems where limits may be more explicit as in the case of the UK ⁴or implicit as in other public health care systems. The minimum level is set outside the model; the process by which α is determined is made explicit through the evaluation of patients' utility function. The expected utility function for a representative individual j can be written as:

$$U^j = M(1 - \lambda t) + \phi H \left(1 - v + v \left(\delta + \lambda \frac{a}{2} \right) \right) \quad (1)$$

where $\lambda = 0$ the new drug is not listed $\lambda = 1$ the drug is listed. For each individual the probability of being ill is a risky event that may occur with probability v . This means that a fraction v of individuals will fall ill and will be treated with the new drug if it is listed.

For this society the expected consumers' surplus without buying the treatment can be found through the aggregation of equation (1) ($\lambda = 0$):

$$CS_{NL} = Y + \phi H (1 - v + v \delta)$$

If the treatment is bought consumers' surplus is equal to:

$$ECS_L = Y \left(1 - \frac{p(1 - \frac{ks}{2})v}{Y} \right) + \phi H \left(1 - v + v \left(\delta + \frac{a}{2} \right) \right)$$

For any given p the decision maker buys the drug if welfare improves from the "doing nothing" option. We can define p^{max} as maximum level of p that it will be paid for the drug: $p^{max} = \frac{1}{2}\phi H a$. This implies that the upper bound for cost effectiveness will be equal to:

$$\alpha = \frac{\frac{1}{2}\phi H a}{\frac{a}{2}H} = \phi$$

It is interesting to note that ϕ is the marginal utility of the health stock; given the assumption of a linear utility it also represents the opportunity cost of treatment in terms of consumption of other goods.

3.2 The rules of the game

The industry proposes to sell the new drug at a price p , but ex post, if the level of effectiveness e falls below the threshold sd a rebate on the price is applied an

⁴In the UK the nice guidelines suggest that treatments whose cost is below £20.000 are approved, between 20 and 30 thousand may be approved and higher than this they will not be in general listed. The debate on these thresholds is quite lively, but they exist.

the firm has to pay back pk so that the price is $p^R = p(1 - k)$. If $e \geq sd$, the full price $p^R = p$ is paid. The expected price under this scheme is defined by :

$$p^R = p - kp \int_0^{sd} \frac{1}{aH} de = p \left(1 - ks \frac{d}{aH} \right) \quad (2)$$

where:

p is the price asked by the industry.

d is the effectiveness that is declared by the industry for reimbursement purposes and that it will have to lie in the interval $(0, a)$.

e is the ex post effectiveness of the drug. At the time of the contract both parties observe its distribution, at a later stage its value will be observed by both parties.

k and s are the parameters of the incentive formula. k is the rebate on the price asked by the regulator if the effectiveness falls below the set level. it takes values between 0 (no rebate asked) and 1 (the full price has to be reimbursed). s is a parameter that describes which effectiveness threshold the new drug will have to reach to be entitled to full price. It may vary between zero (any level of effectiveness) to almost any value. We assume that the upper limit is 1. This means that the maximum effectiveness that can be asked to receive the full price is the declared effectiveness (d)

The formula is asymmetric since the industry pays a penalty if the ex post effectiveness falls short the declared level, but it will not be rewarded if the drug is more effective than declared. The reason for this asymmetry mainly depends on the consideration that the industry may have better information than the regulator on the likely effects of the drug hence it has a strong advantage in setting this parameter.

The probability of being listed L is uniformly distributed within this range (β, α) with a known, uniform probability distribution $v(L)$ with $V(\beta) = 0$ and $V(\alpha) = 1$.

Any drug whose cost effectiveness is beyond ϕ will not be listed while drugs whose cost effectiveness is below β will always be listed. The probability of being can be written as:

$$V(c_E < \phi) = 1 - V(c_E) = \int_{c_E}^{\phi} \frac{1}{\phi - \beta} dc_E$$

3.3 The industry

In this model the industry maximises its expected profit that is given by:

$$Max_p \quad E\Pi = V(c_E < \phi) (p - c) v \quad (3)$$

where v is the number of patients that will be treated with the new drug if it is listed. In general the industry will never have any interest in setting a price

for which $c_E < \beta$. This is a well known downside effect of setting cost effectiveness thresholds ([Jena and Philipson, 2009]), but it may also guide industries in future investment decisions. While in fact the price of low cost technologies may be pushed up since they will be approved, it also make clear from the start that there exists a maximum willingness to pay (ϕ) for a new technology and this may avoid the industry to embark in projects whose costs in terms of both marginal and sunk cost will imply a price higher than society's willingness to pay.

3.4 Benchmark solution

We start our analysis by presenting a benchmark model where there is no risk sharing. In the absence of any other information, the industry will ask a price on the basis of the expected effectiveness ($d = \frac{aH}{2}$), but the system does not foresee any penalty if ex post $e < \frac{aH}{2}$, i.e. $k = 0$. In this case the price can be written as:

$$p_{NR} = p$$

If listed, the industry receives a price equal to p , independently of e , the effectiveness verified ex post.

$$\begin{aligned} \text{Max}_p \quad E\Pi &= \int_{c_E}^{\phi} \frac{1}{\phi - \beta} dc_E (p - c) v & (4) \\ \beta &\leq p \leq \phi \\ c_E &= \frac{2p}{aH} \end{aligned}$$

In appendix A it is shown that the price will be equal to:

$$\begin{aligned} p_{NR}^* &= \frac{1}{2} \left(c + \phi \frac{aH}{2} \right) & \text{for } a \left(\beta - \frac{\phi}{2} \right) \leq c \leq \frac{1}{2} \phi aH \\ p_{NR}^* &= \beta & \text{for } c \leq aH \left(\beta - \frac{\phi}{2} \right) \\ p_{NR}^* &= \phi & \text{for } c \geq \frac{1}{2} \phi aH \end{aligned}$$

In what follows we assume that $\beta < \frac{1}{2}\phi + \frac{c}{a}$ and $c \leq \frac{1}{2}\phi aH$ in order to secure an internal solution.

In this case, the expected profit will be equal to:

$$\begin{aligned} E\Pi_{NR} &= \left(\int_{c_E}^{\phi} \frac{1}{\phi - \beta} dc_E \right) (p_{NR}^* - c) v \\ &= \frac{v}{2aH(\phi - \beta)} \left(\frac{\phi aH}{2} - c \right)^2 \end{aligned}$$

3.5 A simple rebate

Let us now first assume that the price and cost effectiveness are set according to its expected value $\frac{aH}{2}$, but the regulator decides to share with the industry the risk that ex post e falls below $\frac{aH}{2}$ by introducing a rebate k if the threshold $s\frac{aH}{2}$ is not hit. In this case the price can be written as:

$$p_{R1} = p - kp \int_0^{s\frac{aH}{2}} \frac{1}{aH} dE = p \left(1 - \frac{ks}{2} \right)$$

The industry maximises the following function:

$$\begin{aligned} \text{Max}_p E\Pi_{R1} &= \int_{c_E}^{\phi} \frac{1}{\alpha - \beta} dc_E \left(p \left(1 - \frac{ks}{2} \right) - c \right) v \\ c_E &= \frac{2p}{aH} \end{aligned} \quad (5)$$

The FOC can be written as:

$$\frac{\partial E\Pi_{R1}}{\partial p} : \frac{v - 8p + 4kps + 4c + 2\phi aH - \phi aH ks}{2(\phi - \beta)aH}$$

and the optimal price will be equal to:

$$\begin{aligned} p_{R1}^* &= \frac{1}{2} \left(c + \phi \frac{aH}{2} \right) + \frac{1}{2} c \frac{ks}{2 - ks} \\ &= p_{NR}^* + \frac{1}{2} c \frac{ks}{2 - ks} \end{aligned} \quad (6)$$

This allows us to conclude that the price under this risk sharing arrangement is always higher than in the benchmark solution. Since $\frac{\partial p_{R1}^*}{\partial ks} = \frac{c}{(ks-2)^2} > 0$ the increase in the price is higher the closer ks to 1. The industry must accept to bear the risk, but it will ask a higher price. From an economic point of view, the profit as well as the price is important. The expected profit for the industry can be found by substituting (6) into (??) and it is equal to

$$E\Pi_{R1} = \frac{v}{2aH(\phi - \beta)} \left(\frac{\phi aH}{2} - c \right)^2 - \frac{vks}{2(\phi - \beta)} \left(\frac{\phi^2 aH}{8} - \frac{c^2}{(2 - ks)aH} \right) \quad (7)$$

For $ks = 0$, the expected profit is the same as without risk sharing. Intuitively, the profit is going to decrease in ks , hence we can guess that the profit under this agreement is always lower than for risk sharing. A formal proof will be presented in the following sections.

3.6 Risk sharing

In this second model we leave the industry one more degree of freedom. The price and cost effectiveness are set according to the value declared by the industry (d) which may be different from expected effectiveness $\frac{a}{2}$. The regulator decides to share with the industry the risk that ex post is e is below d by introducing a rebate k if the threshold sd is not hit. The industry fully anticipates that the regulator will ask for a risk sharing agreement and the price can be written as:

$$p_{R2} = p - kp \int_0^{sd} \frac{1}{aH} dE = p \left(1 - ks \frac{d}{a} \right)$$

The industry will find the optimal level of p and d that maximises its profit. The problem can be written as:

$$\begin{aligned} \text{Max}_{p,d} E\Pi_{R2} &= \int_{c_E}^{\phi} \frac{1}{\alpha - \beta} dc_E \left(\left(p - kp \int_0^{sd} \frac{1}{aH} dE \right) - c \right) v & (8) \\ d &\leq aH \\ c_E &= \frac{p}{d} \end{aligned}$$

As shown in B, the optimal values for d and p can be written as:

$$d_{R2}^* = \frac{aH}{2ks} \quad (9a)$$

$$p_{R2}^* = p_{NR}^* + \frac{1}{2} \left(c + \frac{\phi aH (1 - ks)}{2ks} \right) \quad (9b)$$

for $ks > \frac{1}{2}$ while for $ks \leq \frac{1}{2}$ it can be written as:

$$d_{R2.2}^* = aH \quad (10a)$$

$$p_{R2.2}^* = p_{NR}^* + \frac{1}{2} \left(c \frac{ks}{1 - ks} + \phi \frac{aH}{2} \right) \quad (10b)$$

In both cases the price is always higher than in the model without risk sharing.

The profit for the industry can be found by substituting the optimal values

for the risk sharing formula into (8). For the first segment where $ks \geq \frac{1}{2}$ the expected profit under this risk sharing agreement will be equal to

$$E\Pi_{R2.1} = \frac{v}{2aH(\phi - \beta)} \left(\frac{\phi aH}{2} - c \right)^2 + \frac{v}{\phi - \beta} \left(\frac{\phi^2 aH}{8} \left(\frac{1}{2ks} - 1 \right) - \frac{c^2}{aH} \left(\frac{1}{2} - ks \right) \right)$$

For the second segment where $ks < \frac{1}{2}$ the expected profit under this risk sharing agreement will be equal to

$$E\Pi_{R2.2} = \frac{v}{2aH(\phi - \beta)} \left(\frac{\phi aH}{2} - c \right)^2 + \frac{v(1 - 2ks)}{2(\phi - \beta)} \left(\frac{\phi^2 aH}{4} - \frac{c^2}{2(1 - ks)aH} \right)$$

4 Discussion

The introduction of risk sharing mechanisms has raised a lively debate on the likely effects of such schemes. Some experts fear that prices and volumes will increase (hence public expenditure) while the industry's argument is that they will be the ultimate losers of these agreements since their profits will be reduced.

Our model does not deal with the issue of volumes (the number of target patients) because in our framework the number is fixed. Our assumption is quite reasonable for the schemes that have been introduced so far which deal with highly specific drugs mostly for strict hospital use on very specific patients. As concerns the two other issues, our model shows that they are both, to some extent, correct. Risk sharing certainly increases prices; for the effects on expected profit we show that the impact on price depends on how fixed are the rules by which the probability of being listed is determined and on how well the industry may be able to foresee changes.

Let us first assume that the listing process remains unchanged after the introduction of risk sharing. In what follows we compare prices and expected profits of the different pricing schemes we have proposed so far.

4.1 Comparing prices

The first claim made by the literature is that the prices of the new drugs will be higher because of the introduction of risk sharing agreements. In the previous section we have already shown that an increase in the price asked by the industry is the likely effect of a risk sharing scheme. Let us now compare prices under the different schemes. Table one summarises the results:

	Label	p	$E(p)$
No risk sharing	NR	$\frac{1}{2} \left(c + \frac{\phi aH}{2} \right) = p_{NR}^*$	p_{NR}^*
Risk sharing 1	$R1$	$p_{NR}^* + \frac{c}{2} \frac{ks}{2 - ks}$	$p_{NR}^* - \frac{\phi aH sk}{8}$
Risk sharing 2	$R2.1$	$p = p_{NR}^* + \frac{1}{2} \left(c + \frac{\phi aH(1 - ks)}{2ks} \right)$ $d = \frac{1}{2} \frac{aH}{ks}$	$p_{NR}^* - \frac{\phi aH(2ks - 1)}{8ks}$ $ks \geq \frac{1}{2}$
Risk sharing 2.2	$R2.2$	$p = p_{NR}^* + \frac{1}{2} \left(c \frac{ks}{1 - ks} + \phi \frac{aH}{2} \right)$ $d = aH$	$p_{NR}^* + \frac{\phi aH(1 - 2ks)}{4}$ $ks < \frac{1}{2}$

Table 1: Prices and expected prices under the risk sharing agreements considered

p is the nominal price received by the industry and the latter is used by the regulator in the listing process. However this price corresponds to what the industry is in fact paid only in the benchmark case, i.e. without any rebate. In all the other cases the nominal price is different from the expected price $E(p)$. The latter is equal to the nominal price paid minus the expected rebate that the industry estimates it will have to pay. In our model we have assumed that the industry uses the expected effectiveness ($\frac{a}{2}$) to determine this price. The ex-post price that the industry receives will depend on the actual verified effectiveness of the new drug. Nominal prices can be ordered as follows:

$$p_{NR}^* < p_{R1}^* < p_{R2}^* < p_{R2.2}^*$$

The price in benchmark is the lowest one while the highest is for a "full risk sharing" and a very low penalty ($ks < 1/2$). It must however be noted that these are the prices asked by the industry, but ex post what the regulator pays may be different according to the risk sharing scheme. The third column of table 1 presents the expected price reimbursed to the industry. In this case the order is

$$Ep_{R1}^* < Ep_{R2}^* < Ep_{NR}^* < Ep_{R2.2}^*$$

The expected price is lower than without risk sharing unless $ks < 1/2$

4.2 Welfare analysis

The listing process may be considered an application to the pharmaceutical industry of the device proposed by [Jaegher and Jegers, 2001] to reduce demand inducement, but it is ex post inefficient since it artificially reduces the benefit from the diffusion of the new drug. In fact, it foresees that drugs that are good value for money may not be listed.

This deadweight loss is necessary to avoid that the firm sets a price equal to ϕ (the maximum willingness to pay) and that all the benefit is transformed into profit. The introduction of risk sharing may allow to reduce this inefficiency through an increase in the probability of being listed. From a total welfare point of view this is indeed the only variable on which to discriminate among risk sharing arrangements. Expected welfare is the sum of consumers surplus and profit multiplied by the probability of being listed, i.e.

$$\begin{aligned} EW &= V(c_E < \phi)(ECS + E\Pi) \\ &= V(c_E < \phi) \left[\left(\frac{\phi a H}{2} - p \right) v + (p - c) v \right] \\ &= V(c_E < \phi) \left(\frac{\phi a H}{2} - c \right) v \end{aligned}$$

Total welfare conditional on being listed is independent of the pricing scheme. This implies that the evaluation of total welfare can be simply made on the

probability of being listed. In appendix C we show that welfare can be ordered as follows:

$$EW_{R2.2} > EW_{NR} > EW_{R2.1} \geq EW_{R1}$$

R2.2 is the best scheme because it increases the probability of being listed while a simple risk shifting mechanism may reduce total welfare if compared with the benchmark solution. The distributional impact of this welfare change can be evaluated by studying the impact of these schemes on the expected profit and on consumers welfare.

4.2.1 Expected profit

Literature on risk sharing often argue that this pricing mechanism reduces prices, hence profits ([Adamski *et al.*, 2010]; [Towse and Garrison, 2010]). While this may be true for profit conditional on being listed, the risk sharing process may alter the probability of being listed and this effect has been largely ignored by the present debate. Let's now examine how the expected profit of the industry is going to change. In table 2 we present a summary. The probability of listing decreases in *R1* and *R2.1* because cost effectiveness increases. For *R2.2* the increase in the declared effectiveness allows to reduce c_E hence listing is more likely. The third column presents the profit conditional on being listed, which is decreasing apart for *R2.2* as one might expect⁵:

$$E\Pi_{R2.2} > E\Pi_{NR} > E\Pi_{R2.1} > E\Pi_{R1}$$

This allows us to conclude that the effect of risk sharing is a decrease in the profit unless $ks < 1/2$. In this case in fact the industry is able to increase the price to a level that more than compensate the possible rebate that the industry will have to pay. In order to keep listing likely the industry also increases d , which implies that paying a rebate is very likely. However, since the penalty is not particularly severe, the industry is better off than without risk sharing.

4.2.2 Consumers' surplus

Let us now examine the effects on consumers surplus. As per the expected profit, we will study separately the effect on the probability of being listed and the surplus conditional on being listed. The effects on the probability are of course the same presented above: the probability of being listed decreases for the scheme *R1* and *R2.1*. The effect on the surplus depends on the marginal cost of production c as shown in appendix. In general, we can conclude that $ECS_{R2.2} < ECS_{NR}$ and that $ECS_{R1} > E\Pi_{R2.1}$

However some interesting conclusions can be drawn. For *R1* and *R2.1* consumers surplus increases only if c is "sufficiently small", in the other cases it decreases. For *R2.1* the surplus conditional on being listed decreases.

Our analysis allows us to conclude that:

⁵See appendix C for a proof.

- If c is sufficiently large $R1$ and $R2.1$ are Pareto inferior solutions since they decrease both consumers welfare and profits. The reallocation of the gross benefit of the drug between the two actors is too costly;
- for c is sufficiently small $R1$ and $R2.1$ total welfare decrease, but consumers are better off.
- $R2.2$ improves total welfare, but it also shifts benefits from consumers' welfare to profit. Unless $ks = 0.5$, consumers are better off in the benchmark case (no risk sharing).

In this respect risk sharing agreements are worse off than NR because the listing is less likely hence total welfare decreases. On the other hand, $R2.2$ improves the expected profits, but a cost of a shifting of benefit from consumers surplus to profit. In this case risk sharing produces a benefit, but only for the industry.

5 The role of the listing process

The model considered so far is based on the assumption that risk sharing does not affect the willingness to pay of the decision maker. However, this assumption may not be justified. In section 3.2 we showed that the probability of being listed depends on the difference between cost effectiveness of the new drug and the maximum cost society is willing to pay for the drug. However, the latter depends itself on the payment system. In this section we show what is the likely effect of the introduction of risk sharing if the regulator evaluates the listing decision on the expected effectiveness of the new drug. In other words, we still assume that the probability of being listed is still defined over the interval (α, β) , but cost effectiveness (c_E) defined using expected price and expected effectiveness. This means that for $R1$ the cost effectiveness is defined as $c_E = \frac{2E(p)}{aH}$ while for $R2.1$ and $R2.2$ it will be equal to $c_E = \frac{E(p)}{E(d)} = c_E = \frac{2E(p)}{aH}$.

We assume that the firm does not anticipate this change, i.e. it assumes that the regulator evaluates c_E on the basis of the declared effectiveness d and the price asked p . The results in terms of price setting as presented in table 1 do not change; however the expected profit and consumer surplus are going to be different as shown in table 3. The welfare analysis of the different risk sharing schemes is presented in appendix D. The results are quite different: total welfare is always increasing unless the penalty ks is "too low". If this is the case, the industry will increase the price and the declared effectiveness, but the expected profit will decrease because of a reduction in the probability of being listed. For the other cases, although in general the expected profit is lower than under no risk, the reduction in the profit is mitigated by an increase in the probability of being listed which in fact increases. In this case consumer surplus is increasing and there is a true redistribution of the benefits of the new drug from the industry to the consumers.

6 Conclusions

Rising drug costs are a challenge to healthcare policy makers because high prices put budgetary pressure on governments that try to maintain access to drugs for the population at an affordable cost.⁶ For this reason, most EU member states control the prices of reimbursable medicines through several instruments ranging from External reference pricing to risk sharing arrangements whose effect is controversial ([Panos *et al.*, 2010]). In this paper we analyse the effects of the introduction of several risk sharing schemes. We show that the price at which the new drug is listed is always higher than in a system without risk sharing, but the expected profit may be greater or lower depending on the parameters of the listing process and on how the process itself is affected by the introduction of risk sharing. This consideration has important policy implications: in the presence of risk sharing the price is not a good proxy for value for money. It is only ex post, when the true effectiveness will be known that value for money can be evaluated. In a risk-sharing agreement in fact it is necessary to take account of the rebates that the firm may incur if the effectiveness falls short of what promised.

In general the expected profit is always lower than without a risk sharing agreement unless $ks < \frac{1}{2}$. Our analysis is however able to point out some important shortcomings of these schemes. For drugs whose production costs is sufficiently higher risk sharing agreements may be Pareto inferior to no risk sharing because they reduce the expected profit and the expected consumers surplus. This is the result of the effect that the increase in price has on the probability of listing. This shortcoming may be avoided by an appropriate choice of the parameters to use for listing. In our case, the use of the expected price and expected effectiveness to determine ICER allows to shift benefits from the industry to consumers and it increases total welfare.

In this case it is however interesting to note that expected profit for low penalties ($ks < 1/2$) is lower than in the benchmark. Although the penalty is very low, the industry will ask a higher price for the drug if it anticipates a risk sharing mechanism, but this sensibly reduces the probability of being listed.

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⁶In Europe, about 75% of pharmaceutical expenditure is reimbursed from public funds ([OECD, 2012])

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7

A Optimal price without risk sharing

$$Max_p \quad E\Pi = \int_{c_E}^{\alpha} \frac{1}{\phi - \beta} dc_E (p - c) x \quad (11)$$

$$\beta \leq p \leq \alpha \quad (12)$$

Let us start by assuming that the constraint is satisfied. The F.O.C. in this case can be written as:

$$\frac{\partial E\Pi}{\partial p} : v \frac{4p - 2c - \phi a}{(-\phi + \beta) a} = 0$$

and the optimal price will be equal to:

$$p_{NR}^* = \frac{1}{2} \left(c + \phi \frac{a}{2} \right)$$

This solution is valid only if $a \left(\beta - \frac{\phi}{2} \right) \leq c \leq \frac{1}{2} \phi a$. In the other cases the constraint is binding and the price will be

$\underline{p} = \beta$ and $\bar{p} = \phi$. In the latter case, the profit will however be negative.

B Derivation of the optimal price and declared effectiveness

The problem can be written as:

$$Max_{p,d} \quad E\Pi_{R2} = \int_{c_E}^{\phi} \frac{1}{\phi - \beta} dc_E \left(\left(p - kp \int_0^{sd} \frac{1}{a} dE \right) - c \right) v$$

$$d \leq a \quad (13)$$

Let us first assume that the constraint is satisfied. In this case the problem can be solved as an unconstrained maximisation and the FOC can be written as:

$$\frac{\partial E\Pi}{\partial p} : -v \frac{2pa - 2kpsd - ca - \phi da + \phi d^2 ks}{(\phi - \beta) da} = 0$$

$$\frac{\partial E\Pi}{\partial d} : vp \frac{pa - \phi d^2 ks - ca}{(\phi - \beta) d^2 a} = 0$$

and the optimal values for d and p can be written as:

$$\begin{aligned}
d_{R2}^* &= \frac{1}{2} \frac{a}{ks} \\
p_{R2}^* &= p_{NR}^* + \frac{1}{2} \left(c - \frac{ks-1}{2ks} a\phi \right)
\end{aligned} \tag{14a}$$

This solution is valid only if $ks \geq \frac{1}{2}$; if this condition is not satisfied, $d > a$. Given that d_{R2}^* is increasing in ks , for $ks < \frac{1}{2}$, $d = a$ and the problem can be written as:

$$Max_{p,d} E\Pi = \int_{c_E}^{\phi} \frac{1}{\phi - \beta} dc_E \left(\left(p - kp \int_0^{sa} \frac{1}{a} dE \right) - c \right) \tag{15}$$

The FOC can be written as:

$$\frac{\partial E\Pi}{\partial p} : \frac{c - (2p - \phi a)(1 - ks)}{(\phi - \beta)a} = 0$$

and the optimal solution can be written as:

$$d_{R2.2}^* = a \tag{16a}$$

$$p_{R2.2}^* = p_{NR}^* + \frac{c}{2} \left(\frac{ks}{1 - ks} \right) \tag{16b}$$

C Comparing schemes: first case

C.1 Comparing profits

The third column of table 3 reports the profit conditional on being listed. For $R1$, given that $ks \geq 1/2$, $\frac{2ks-1}{ks} > 0$ the profit is lower than without risk sharing. For $R2.2$ $1 - 2ks > 0$ which implies that the profit is always greater than without risk sharing.

Let us now evaluate the probability of being listed. For $R1$ we can conclude that $RS1 < Rnorisk$ unless $ks = 0$; $RS2.1 < RNR$ unless $ks = 1/2$ and finally $RS2.1 > RNR$ unless $ks = 1/2$.

In this case since the difference in the profit conditional on being listed and the probability of being listed go in the same direction we can conclude that expected profit will decrease with risk sharing unless $ks < 1/2$. To order all the cases we need to compare profit under $R1$ and $R2.1$.

The difference between $R1$ and $R2.1$ can be written as:

$$\Delta = -\frac{v}{2\phi-2\beta} ks \left(\frac{1}{8} \phi^2 aH - \frac{c^2}{(2-ks)aH} \right) + \frac{v}{\phi-\beta} \left(\frac{1}{8} \phi^2 aH \left(1 - \frac{1}{2ks} \right) - \frac{c^2}{aH} \left(ks - \frac{1}{2} \right) \right)$$

and ks varies between $1/2$ and 1

for $ks = 1/2$ $\Delta < 0$ $R1 < R2.1$

for $ks = 1$ $\Delta = 0$

Since Δ is increasing in ks , we can conclude that:

$$E\Pi_{R2.2} > E\Pi_{NR} > E\Pi_{R2.1} \geq E\Pi_{R1}$$

C.2 Comparing CS

The third column of table 3 also reports the consumer surplus conditional on being listed. For $R1$, given that $ks \geq 1/2$, $\frac{2ks-1}{ks} > 0$ CS is higher than without risk sharing. For $R2.2$ $1-2ks > 0$ which implies that CS is always lower without risk sharing.

For the probability of listing the same consideration made for profit are still valid, but in this case we need to evaluate the differences in expected CS because the effect on the probability of listing and CS conditional on being listed is countervailing.

For $R1$ we need to evaluate the sign of the expression $\frac{vks}{2(\phi-\beta)} \left(\frac{1}{8}\phi^2 aH - \frac{1}{2-ks}\phi c + \frac{c^2}{(2-ks)aH} \right)$. For $ks = 0$ it is equal to zero as one might expect. Let us now evaluate the derivative of this expression with respect to ks . It is equal to $\frac{v}{\phi-\beta} \left(\phi^2 \frac{aH}{16} - \frac{\phi aH - c}{aH} \frac{c}{(2-ks)^2} \right)$ and its sign depends on c . For $R2.1$ we need to evaluate the sign of the expression $-\frac{v(1-2q)}{2(\phi-\beta)} \left(-\phi c + \frac{c^2}{aH} + \frac{1}{8}\phi^2 a \frac{H}{q} \right)$. For $ks = 1/2$ it is zero. The derivative for ks is equal to $\frac{v}{(\phi-\beta)} \left(\frac{1}{16}\phi^2 a \frac{H}{q^2} - (\phi aH - c) \frac{c}{aH} \right)$ which again depends on c .

For $R2.2$ the difference in expected CS is equal to $-\frac{v(1-2ks)}{4(\phi-\beta)} \left(\frac{1}{2}\phi^2 aH - \phi \frac{c}{1-ks} + \frac{c^2}{(1-ks)aH} \right)$ which is 0 for $ks = 1/2$.

The derivative for ks is equal to $\frac{v}{4(\phi-\beta)} \left(\phi^2 a \frac{H}{1} - \frac{\phi aH - c}{aH} \frac{c}{(-1+q)^2} \right)$ but in this case it is positive for any value of c in the range $0 \leq c \leq \phi \frac{aH}{2}$. Since ks varies between $1/2$ and zero, CS is always lower than without risk sharing.

For total welfare, it is sufficient to evaluate the differences in the probability of being listed and we can conclude that

$$EW_{R1} > EW_{R2.1} > EW_{NR} \geq EW_{R2.2}$$

D Comparing schemes second case

D.1 Comparing profits

Let us start by the probability of being listed. We can conclude that $R1 > RNR$ unless $ks = 0$; $R2.1 > RNR$ unless $ks = 1/2$ and $R2.2 < RNR$ unless $ks = 1/2$.

The profit conditional on being listed in table 3 is the same as in table 2; this imply that to evaluate the final impact of this scheme on expected profit we have to analyse the equations presented in column 4 of table 3.

For $R1$ profit is lower with a risk sharing scheme unless $ks = 0$; for $R2.1$ and $R2.2$ expected profit is lower unless $k = 1/2$. In order to order profit, the

differences in expected profit need to be evaluated. Let us start with $R1 - R2.1$. In this case the difference is $\left(\left(\frac{1}{2ks} - 1\right)^2 - \frac{s^2 k^2}{4}\right) \frac{vHa\phi^2}{8(\phi-\beta)}$ which is equal to 0 for $ks = 1$ and it is then increasing as ks decreases. The difference $R1 - R2.2$ is equal to $\left(\frac{15}{16}s^2 k^2 + \frac{1}{4} - ks\right) \frac{vHa\phi^2}{2(\phi-\beta)}$ which is equal to 0 for $ks = 1/2$ and then it increases as ks decreases.

$$E\Pi_{NR} > E\Pi_{R1} > E\Pi_{R2.1} \geq E\Pi_{R2.2}$$

D.2 Comparing CS

The third column of table 3 also reports the consumer surplus conditional on being listed. For $RS1.1$, given that $ks \geq 1/2$, $\frac{2ks-1}{ks} > 0$ CS is higher than without risk sharing. For $RS2.2$, $1 - 2ks > 0$ which implies that CS is always lower without risk sharing.

For the probability of listing the same consideration made for profit are still valid. For CS however the change in the probability of listing and surplus conditional on being listed go in the same direction, hence we can conclude that expected surplus is increasing with $R1$ and $R2.1$ while it is decreasing for $R2.2$. To order the profits we need to evaluate the difference between $R1$ and $R2.1$ which is equal to $\frac{v}{2(\phi-\beta)} \left(aH\phi^2 \left(\left(\frac{ks}{4} + \frac{1}{2}\right)^2 - \left(\frac{1}{4ks} - 1\right)^2 \right) - \left(\frac{(ks-1)^2}{ks}\right) \frac{c\phi}{2} \right)$ which is zero for $ks = 1$ and it then depends on c .

$$ECS_{R1} > ECS_{R2.1} > ECS_{NR} \geq ECS_{R2.2}$$

D.3 Comparing welfare

For welfare, it is sufficient to use the probability of being reimbursed. We need to order $R1$ and $R2.1$. The difference can be written as: $\frac{1}{4} \frac{\phi}{\phi-\beta} \left(\frac{(ks-1)^2}{ks} \right)$ which is always positive, hence $EW_{R1} > EW_{R2.1}$. The order will then be:

$$EW_{R1} > EW_{R2.1} > EW_{NR} \geq EW_{R2.2}$$

Regime	Prob listing	Profit*	Expected Profit
No risk sharing	$\frac{\phi aH - 2c}{2(\phi - \beta)aH}$	$\frac{v}{2} \left(\frac{\phi aH}{2} - c \right)$	$\frac{v}{2aH(\phi - \beta)} \left(\frac{\phi aH}{2} - c \right)^2$
Risk sharing 1	$\frac{\phi aH - 2c}{2(\phi - \beta)aH} - \frac{cks}{(\phi - \beta)(2 - ks)aH}$	$\frac{v}{2} \left(\frac{\phi aH}{2} - c \right) - \frac{v}{8} \phi aH ks$	$\frac{v}{2aH(\phi - \beta)} \left(\frac{\phi aH}{2} - c \right)^2 - \frac{v}{2(\phi - \beta)} ks \left(\frac{1}{8} \phi^2 aH - \frac{c^2}{(2 - ks)aH} \right)$
Risk sharing 2.1	$\frac{\phi aH - 2c}{2(\phi - \beta)aH} - \frac{c(2ks - 1)}{(\phi - \beta)aH}$	$\frac{v}{2} \left(\frac{\phi aH}{2} - c \right) - \frac{v}{8} a \phi H \frac{2ks - 1}{ks}$	$\frac{v}{2aH(\phi - \beta)} \left(\frac{\phi aH}{2} - c \right)^2 - \frac{v}{\phi - \beta} \left(\frac{\phi^2 aH}{8} \left(\frac{2ks - 1}{2ks} \right) - \frac{c^2}{aH} \left(ks - \frac{1}{2} \right) \right)$
Risk sharing 2.2	$\frac{\phi aH - 2c}{2(\phi - \beta)aH} + \frac{c(1 - 2ks)}{2(\phi - \beta)(1 - ks)aH}$	$\frac{v}{2} \left(\frac{\phi aH}{2} - c \right) + \frac{v}{4} \phi aH (1 - 2ks)$	$\frac{v}{2aH(\phi - \beta)} \left(\frac{\phi aH}{2} - c \right)^2 + \frac{v(1 - 2ks)}{2(\phi - \beta)} \left(\frac{\phi^2 aH}{4} - \frac{1}{2} \frac{c^2}{(1 - ks)aH} \right)$
Regime	Prob listing	Consumers Surplus	Expected Consumers Surplus
No risk sharing	$\frac{\phi aH - 2c}{2(\phi - \beta)aH}$	$\left(\frac{\phi aH}{2} - c \right) \frac{v}{2}$	$\frac{v}{2aH(\phi - \beta)} \left(\frac{\phi aH}{2} - c \right)^2$
Risk sharing 1	$\frac{\phi aH - 2c}{2(\phi - \beta)aH} - \frac{cks}{(\phi - \beta)(2 - ks)aH}$	$\frac{v}{2} \left(\frac{\phi aH}{2} - c \right) + \frac{v}{8} \phi aH ks$	$\frac{v}{2aH(\phi - \beta)} \left(\frac{\phi aH}{2} - c \right)^2 + \frac{vks}{2(\phi - \beta)} \left(\frac{\phi^2 aH}{8} - \frac{1}{2 - ks} \phi c + \frac{c^2}{(2 - ks)aH} \right)$
Risk sharing 2	$\frac{\phi aH - 2c}{2(\phi - \beta)aH} - \frac{c(2ks - 1)}{(\phi - \beta)aH}$	$\frac{v}{2} \left(\frac{\phi aH}{2} - c \right) + \frac{v}{8} \phi aH \frac{2ks - 1}{ks}$	$\frac{v}{2aH(\phi - \beta)} \left(\frac{\phi aH}{2} - c \right)^2 - \frac{v(1 - 2ks)}{2(\phi - \beta)} \left(\frac{c^2}{aH} + \phi^2 a \frac{H}{8ks} - \phi c \right)$
Risk sharing 2.2	$\frac{\phi aH - 2c}{2(\phi - \beta)aH} + \frac{c(1 - 2ks)}{2(\phi - \beta)(1 - ks)aH}$	$\frac{v}{2} \left(\frac{\phi aH}{2} - c \right) - v \frac{\phi aH(1 - 2ks)}{4}$	$\frac{v}{2aH(\phi - \beta)} \left(\frac{\phi aH}{2} - c \right)^2 - \frac{v(1 - 2ks)}{4(\phi - \beta)} \left(\frac{\phi^2 aH}{2} - \phi \frac{c}{1 - ks} + \frac{c^2}{(1 - ks)aH} \right)$

Table two: Welfare analysis of risk sharing

Regime	Prob listing	Profit	Expected profit
No risk sharing	$\frac{1}{2} \frac{\phi a H - 2c}{(\phi - \beta) a H}$	$\frac{v}{2} \left(\frac{\phi a H}{2} - c \right)$	$\frac{v}{2 a H (\phi - \beta)} \left(\frac{\phi a H}{2} - c \right)^2$
Risk sharing 1	$\frac{1}{2} \frac{\phi a H - 2c}{(\phi - \beta) a H} + \frac{1}{4} \frac{\phi a H k s}{(\phi - \beta) a H}$	$\frac{v}{2} \left(\frac{\phi a H}{2} - c \right) - \frac{v}{8} \phi a H k s$	$\frac{v}{2 a H (\phi - \beta)} \left(\frac{\phi a H}{2} - c \right)^2 - \frac{1}{32} v \phi^2 s^2 \frac{k^2}{\phi - \beta} a H$
Risk sharing 2	$\frac{1}{2} \frac{\phi a H - 2c}{(\phi - \beta) a H} + \frac{1}{4} \frac{\phi a H}{a H (\phi - \beta)} \left(\frac{2ks-1}{ks} \right)$	$\frac{v}{2} \left(\frac{\phi a H}{2} - c \right) - \frac{v}{8} a \phi H \frac{2ks-1}{ks}$	$\frac{v}{2 a H (\phi - \beta)} \left(\frac{\phi a H}{2} - c \right)^2 - \left(\frac{1}{2ks} - 1 \right)^2 \frac{\phi^2 v a H}{8(\phi - \beta)}$
Risk sharing 2.2	$\frac{1}{2} \frac{\phi a H - 2c}{(\phi - \beta) a H} - \phi a H \left(\frac{1-2ks}{2(\phi - \beta) a H} \right)$	$\frac{v}{2} \left(\frac{\phi a H}{2} - c \right) + \frac{v}{4} \phi a H (1 - 2ks)$	$\frac{v}{2 a H (\phi - \beta)} \left(\frac{\phi a H}{2} - c \right)^2 - \left(\frac{1}{2} - ks \right)^2 \frac{v}{2(\phi - \beta)} \phi^2 a H$
No risk sharing	$\frac{1}{2} \frac{\phi a H - 2c}{(\phi - \beta) a H}$	$\left(\frac{\phi a H}{2} - c \right) \frac{v}{2}$	Expected Consumers surplus
Risk sharing 1	$\frac{1}{2} \frac{\phi a H - 2c}{(\phi - \beta) a H} + \frac{1}{4} \frac{\phi a H s k}{(\phi - \beta) a H}$	$\frac{v}{2} \left(\frac{\phi a H}{2} - c \right) + \frac{v}{8} \phi a H k s$	$\frac{v}{2 a H (\phi - \beta)} \left(\frac{\phi a H}{2} - c \right)^2 + \frac{v \phi}{8(\phi - \beta)} k s \left(\phi a H \left(1 + \frac{ks}{4} \right) - 2c \right)$
Risk sharing 2	$\frac{1}{2} \frac{\phi a H - 2c}{(\phi - \beta) a H} + \frac{1}{4} \frac{\phi a H}{a H (\phi - \beta)} \left(\frac{2ks-1}{ks} \right)$	$\frac{v}{2} \left(\frac{\phi a H}{2} - c \right) + \frac{v}{8} \phi a H \frac{2ks-1}{ks}$	$\frac{v}{2 a H (\phi - \beta)} \left(\frac{\phi a H}{2} - c \right)^2 + \frac{v}{2(\phi - \beta)} \left(\left(\frac{1-2ks}{2ks} \right) \phi c + \left(\frac{4ks-1}{16s^2 k^2} - \frac{1}{4} \right) a H \right)$
Risk sharing 2.2	$\frac{1}{2} \frac{\phi a H - 2c}{(\phi - \beta) a H} - \phi a H \left(\frac{1-2ks}{2(\phi - \beta) a H} \right)$	$\frac{v}{2} \left(\frac{\phi a H}{2} - c \right) - \frac{v}{4} \phi a H (1 - 2ks)$	$\frac{v}{2 a H (\phi - \beta)} \left(\frac{\phi a H}{2} - c \right)^2 + \frac{v}{\phi - \beta} \left(\left(\frac{1-2ks}{2} \right) \phi c + \left(s^2 k^2 - \frac{1}{4} \right) \frac{\phi^2 a H}{2} \right)$

Table 3: Welfare analysis when the listing process is updated