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Optional delinked reward system (ODRS)

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1. INTRODUCTION

A “fair” price for new pharmaceutical products must meet three objectives: (1) it must be “fair” as between buyer and seller, ensuring especially that poor buyers can afford to meet their health needs while firms’ investments are rewarded appropriately; (2) it must be “fair” as between different sellers, ensuring that the rules for what will be rewarded are clear and not arbitrarily enforced; and (3) it must be “fair” as between countries, so that each makes an appropriate contribution to support the global investment in innovation.

The current systems of pricing pharmaceuticals fail on all three counts. With respect to the first, there is a constant struggle to ensure that prices do not create an insuperable obstacle to access, given that buyers have very different financial capacities. A price that is no barrier to access to an insured patient in France may be unaffordable for patients (and insurers) in Bulgaria. High prices often inhibit access to drugs for rare diseases even in wealthy countries. At the same time, firms often feel that their investments are inadequately compensated. With respect to achieving fairness between different sellers, the current system also fails. The problem is that in most countries, confidential price negotiations and an absence of transparency allow insurers to exploit their pricing power, with small companies being particularly disadvantaged on account of less information and less bargaining power. And with respect to achieving fairness between countries, it is clear that countries contribute towards investment in innovation at very different rates: just within the OECD there are wide variations in the share of GDP spent on pharmaceuticals, ranging from 0.6% to 2.9%.⁽¹⁾

Can we do better?

This paper shows how an Optional Delinked Reward System (“ODRS”) can make progress on all three dimensions of fairness. By “delinking” the price paid by consumers or hospitals from the reward paid to the innovator, it is possible to achieve efficient pricing, and thus support access to medicines even by the poor, while a separate payment supports innovation. Such a reward can and should be both transparent and based on transparent rules, in order to ensure fairness and predictability across firms and products. In addition, this model of dual payments can enable countries to offer different reward levels that recognize their different income levels, without inducing arbitrage across countries. In summary, the ODRS can advance “fairness” in pharmaceutical pricing in all three dimensions.

The challenges in our current system stem from trying to do too much with a single tool: price. Pharmaceutical policies must address at least two objectives: encouraging “optimal” *innovation* and enabling the widest efficient access. The implication of this is clear: a single price will not be



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adequate to meet both objectives, any more than a single arrow can strike two different targets. The relevant principle, formalized as the Tinbergen Rule, is that policy-makers require as many independent instruments as they have objectives.(2)

The efficient price to optimize access alone is well-known: it is equal to marginal cost, unless there are externalities, such as the risk of infection. The marginal cost to supply a patient or an insurer should include the costs of production, distribution, and retailing, but exclude the research and development costs. It is, in effect, like a competitive generic price. In some cases, there may be a justification for even lower prices, as when the drug limits an infectious disease.

A price equal to marginal cost will fail to incentivize optimal innovation; a separate payment, not tied to access, is required. This separate payment can be designed to be transparent, and to reflect social preferences for innovation and a fair contribution towards the global goals for improved medicines. The ODRS is built on these principles. However, it is important to recognize that the proposal is not a panacea, and it would poorly suit some types of pharmaceutical innovation. This is why the ODRS is an optional system, filling in some gaps, and designed to advance the three types of fairness described above, but not to be a single tool to achieve a pharmaceutical utopia.

The following sections briefly describe how the ODRS would operate, and then why the proposed mechanism would deliver value to patients and industry. Sections 4 and 5 explain the implementation of the ODRS in greater detail, and what sort of products would likely be most suitable for this model. Section 6 shows how the ODRS can be used in an international context. Sections 7 and 8 comment on challenges that would face its implementation, and offer a closing summary.

2. ODRS DESIGN

The ODRS is designed as a complement to existing systems of insurance. It would create an **option** for firms selling patented drugs: they could either continue with business as usual, or elect payment through the ODRS. The latter would entail two separate payments to the supplier: (a) a **price per unit** of the product equal to the average cost of production and distribution, which would roughly equal the price that one would expect following generic entry and (b) a **reward for innovation**, based on the assessed incremental health benefits resulting from use of a medicine, compared to the existing standard of care. The reward should offer a fixed price (e.g., £50,000) per unit of health benefit (e.g., per incremental Quality-Adjusted Health-Year (QALY)). Assuming a limited budget, the reward could contemplate equiproportionate reductions in rewards for all participants, if the proposed rewards exceeded the budget. In this way, firms would compete for the limited budget based on the health benefits their products achieved. The unit price would be paid under existing systems of insurance or out-of-pocket in the normal course. The annual reward payment to the firm would equal the reward per QALY times the incremental number of QALYs achieved by the product, with deductions for the product sales revenues and net additional costs required for its use. (Additional details on payment determination are included in Section 4.)

Rewards could be paid over a period of years – ten seems appropriate, to match the average exclusivity period of new drugs in most markets – based on annual assessed health benefits.



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Following the ten-year period, the firm would be obliged to permit generic competitors to supply the drug. Thus, the sales price could be expected to continue at about the same level after generic entry as before.

If assessed benefits are the measure of success, then it is necessary to have a way of valuing those benefits: the standard, though imperfect, measure is something like incremental Quality-Adjusted Life-Years, or QALYs, delivered by the use of the medicine rather than the pre-existing standard of care. Measurement of health benefits need not be an insuperable barrier; in the context of a country like the UK, there is already a considerable investment in estimating QALYs for new products. What would be required beyond the current efforts is to track how those drugs were being used, particularly when there are multiple indications. In some cases, tracking patient demographics might also be useful in estimating health benefits. Some drugs also have post-approval clinical trial and reporting requirements and, where appropriate, these data could also be used. **It isn't proposed that real-world outcomes be used to assess health benefits;** instead, assessment should be based on clinical trial data, modified appropriately for relevant measurable characteristics of usage such as indications. This is not a pay-for-performance model in which the drug is not reimbursed if the patient doesn't get better.

The ODRS is here conceived as a supplementary national system of insurance, funded by existing national or private insurers. However, as described in Section 6, the ODRS could be implemented collaboratively by a group of countries.

Further discussion of the details of the implementation of the ODRS is postponed until after a discussion of the rationale for this addition to the system of insurance and drug pricing.

3. RATIONALE FOR THE ODRS

The ODRS could offer numerous benefits both to patients and to innovative firms, as discussed below. It would create a backstop on pricing to constrain opportunistic behaviour by insurers. It could avoid entry delays caused by Health Technology Assessment (HTA) processes and price negotiation, which in many countries result in years in which patients are unable to access drugs and firms are unable to earn revenues. In addition, it could better manage pricing in various settings, including for multi-indication drugs and orphan drugs.

3.1 THE ODRS AS A COMMITMENT MECHANISM

The problem. A challenging feature of many national drug markets is that the innovator must invest heavily to bring a drug to the point of market approval, and only then seek a price based on a health technology assessment. At that point, the bargaining power of the firm is quite weak: the drug development and approval costs are sunk. It will earn nothing from sales to the patients of an insurer if no agreement is reached over price. In contrast, the net benefit to the insurer from accepting a new drug into the formulary is likely to be small, given opportunity costs. Moreover, insurers can exercise monopsony power, which results in strategic behaviour to reduce prices. (3) Buyers are estimated to hold 55% of the bargaining power, and it is apparent that buyer size and history can have a large impact on the prices paid.(4,5)



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To be concrete about the opportunism problem, consider a simple example. A firm believes that it will be profitable to invest in developing a new drug if it can obtain a price of at least \$15,000 per QALY. The drug will have low production costs of \$1,000 per QALY. The insurer has a willingness to pay (WTP) per QALY of \$20,000. Once the firm has developed the drug, R&D costs are sunk and in principle, the Willingness to Accept (WTA) of the supplier is \$1,000, just enough to cover production costs. In a negotiation, we would not normally expect the price to end up at \$20,000. The Nash Bargaining Solution, assuming equal bargaining power, would be a price in the middle, at \$10,500.⁽⁶⁾ The firm, looking forward to its position after it has already invested in R&D, will not be willing to invest at all. The problem here is that the negotiation takes place *after* the innovator has already invested. Given the willingness to pay of \$20,000, the insurer should welcome innovations that can be commercialized for a price per QALY under \$20,000; but it will not obtain those innovations, since firm will anticipate opportunistic behaviour by the insurer after the firms have already invested.

Moreover, at an international level there is the problem of free riding on high prices in other countries. The incentives to support research through high prices in any given country are weak, since each country's individual influence on the course of research globally is relatively small. A similar problem occurred in innovation generally, and this was resolved through the World Trade Organization's agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), through which each country committed to a minimum patent standard of 20 years. While this agreement has been broadly effective in supporting innovation, its application to pharmaceuticals has been impaired through monopsony power of insurers in bargaining down prices. From the perspective of an investor in an innovative firm, a 20-year patent is not much good if the price is depressed. (For consumer goods in which private choice determines demand, the same problem does not arise: an individual consumer cannot push the price down. The problem of opportunism by insurers arises because they can exercise monopsony power in the markets in which they operate.)

In principle, in the example above, the insurer could create efficient incentives for investment in innovation by committing to a price of \$20,000. However, as described above, short-run incentives to get low prices conflict with this long-run goal of supporting innovation. Indeed, to an increasing extent, insurers are using confidential price negotiations to set real prices far below nominal public prices.⁽⁷⁾ This means that it is increasingly difficult for firms to know what prices are being paid, and increasingly difficult for insurers to earn a reputation as offering a fair price. The reliance on confidential prices internationally has aggravated the problems of opportunism since, with confidential pricing, it has become impossible for insurers to signal their willingness to pay.

ODRS as a solution. **Commitment** is the key contribution of the ODRS in this context. By publicly establishing a standard payment per QALY, the ODRS would help investors to know the minimum reward that they could expect. In effect, giving firms a choice protects them: if they don't feel that the price they can negotiate with insurers is fair, they can turn to the ODRS as a **backstop**. To be sure, for the ODRS to be effective in this role, it needs to be adequately financed. But the key point here is that in the long run, offering a fair reward to innovators is crucial to supporting investment in innovation. The ODRS offers a novel way to provide this financial support.



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3.2 THE ODRS MINIMIZES MARKET ENTRY DELAYS

The problem. Under existing mechanisms, in many countries there are lengthy delays in patient access to new drugs caused by HTA processes and price negotiations. For example, in most European countries, economic appraisal does not start until after a positive CHMP decision, resulting in substantial access delays for most drugs after EMA approval.(8) In Canada, the combination of HTA and the negotiation process delays access to new therapies by an average of 602 days.(9) Similar “reimbursement lags” occur in Australia, S. Korea and Taiwan.(10) Moreover, in many countries, there are delays to HTA applications because of external reference pricing.(11)

The delays to effective market entry have potentially enormous costs. From the perspective of pharmaceutical innovators, rapid access is the prerequisite to rapid revenues, offering not only an earlier return on their investment, but a longer effective duration of patent protection. Rapid access thus has the effect of increasing the returns on investment in pharmaceutical innovation. For the population, earlier access and more innovation hold out the promise of better health outcomes. (12) Delays in access have the opposite effect: for example, delayed access to oncology drugs in Canada is estimated to result in a substantial loss in life-years.(13)

ODRS as a solution. Products entering the ODRS would face an HTA process that would occur *after* they had already begun selling, with payment to follow. The ODRS option would thus allow firms to **avoid time-consuming HTA processes and price negotiations** with insurers before their product entered the market. That would allow new medicines to get to patients faster, and for firms to begin to be reimbursed for sales that could start immediately following marketing authorization.

The reason that this would work is that, through the commitment of the ODRS, the reward would be determined according to pre-agreed rather than negotiated on a case-by-case basis. With a low sales price, products in the ODRS could be purchased by consumers even prior to a formulary listing by insurers, although generally one would expect insurers to treat them in the same way as generic drugs. And the ODRS, as insurer, would be protected by a performance-related contract with the firm: it would not face the risk of paying high prices for a drug that turned out to be used mostly in low-value indications. The ODRS, by offering a *fair* reimbursement scheme, enables this efficient outcome that can benefit both investors and patients.

3.3 THE ODRS MINIMIZES THE RISK THAT HIGH PRICES INHIBIT USE

The problem. High prices inhibit appropriate use of pharmaceuticals. Many drugs, and especially those that address the needs of small patient populations, are priced at levels that inhibit usage, a phenomenon that is observed regardless of insurance status. For uninsured patients, high prices naturally deter use: patients do not fill prescriptions, or split pills to stretch out the effect; or in some cases clinicians may be deterred from even writing prescriptions in the first place. While most people in OECD countries have insurance for prescribed drugs, price still limits access in important ways.

First, the decision by the insurer whether to include the drug in the formulary and for which indications or with what restrictions is often driven by the price. Thus, access can be restricted by the insurer because of price, even before the patient comes into view. Moreover, patients often



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face proportional co-payments. For example, in some Canadian provinces, patients pay a co-payment of 30% of the drug price. This leads, not surprisingly, to cost-based non-adherence. (14)

Pricing affects usage in hospital settings as well. In many systems, such as the NHS, local authorities (e.g., “Integrated Care Systems”) with fixed budgets are given further incentives through prices to minimize the use of costly therapies, even if the therapies are approved for insurance coverage. For example, in the Antibiotic Subscription Pilot in the UK, even though the per unit payment by the NHS to the company is zero, the transaction price faced by hospitals for acquiring antibiotics under the pilot is positive, so that there will be appropriate use of these products. Price plays an important role in the management of health systems because it is a clear, transparent signal.

As a signal, an inefficiently high price is a failure. When the true marginal cost of treating another person is only the cost of manufacturing some additional pills, but the price is a thousand times as high, the insurer, local authorities, prescribers and perhaps patients receive the wrong signal about the true cost. To put this another way, once research and development costs have been incurred, they are “sunk” (in the jargon of economics) and cannot be recovered. The true social costs of supplying another tablet are therefore only the production and distribution costs. Efficiency requires that the price reflect only these costs.

ODRS as a solution. The ODRS can help to address this because the transaction price for products in the ODRS reflects only variable costs. This will lead to **socially efficient purchasing and prescribing**. Insurers will not exclude ODRS products from the formulary or impose usage limitations because of high prices. And patients will not be deterred from use because of high prices or high co-payments.

An instructive example of how price matters is international experience with direct-acting antivirals (DAAs) for HCV. It was evident from the beginning that all patients with hepatitis C infections should be treated with these highly effective drugs, but because of pricing, access to the drugs was limited in many countries based on the expected benefit. (15–17) This was doubly problematic: not only were many patients denied access on the basis of cost, untreated patients remained more likely to infect others. In order to avoid price creating a deterrent to treatment, in 2016 Australia committed A\$1.2bn for five years to obtain unlimited DAAs in a risk-sharing agreement with pharmaceutical companies. In effect, this resembled a kind of ODRS, though specific to DAAs. The result was an accelerated uptake of these important drugs, enabling Australia to rapidly move towards elimination. A recent analysis shows that there was a large saving in healthcare costs and an even larger gain in productivity, compared to the case without this strategy.(18)

3.4 THE ODRS ENABLES EFFICIENT INCENTIVES FOR NEW INDICATIONS

Many drugs have multiple indications (or could have additional indications), but current pricing models provide weak incentives to develop additional indications and create inappropriate incentives for usage. These problems are linked and are challenging to solve.

Problem 1. Consider first the problem of pricing drugs with multiple indications. On average, new drugs have about two indications. (19) Often, the indications have very different health benefits.



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For example, the health benefits of trastuzumab provided to late-stage breast cancer patients are three times larger than the ones provided to early-stage patients.⁽²⁰⁾ Ideally the price of the drug might differ across indications to reflect the value in each indication. However, in our current pricing systems, it is difficult to offer a low price for one indication and a high price for another because of arbitrage.

There are three typical responses. The first is for the firm to engage in price discrimination by separating out the products. An example is Pfizer's pricing of sildenafil, which is available in 25mg, 50mg, and 100mg for erectile dysfunction or as 20mg tablet for pulmonary arterial hypertension. By keeping the dosages different, Pfizer was able to set distinct prices.⁽²¹⁾ Unfortunately, this strategy is not always implementable, particularly if the different indications require similar dosages.

A second response is to set a price based on the average value of all indications.^(20,22) While this requires tracking usage by indication, it still results in a distorted price signal. For a drug that has two uses with very different therapeutic effects, a price based on the average will be too low for one and too high for the other.

The third, and probably most common, outcome is for the price to be set based on the first approved indication, and to remain at that level, even if subsequent indications have very different benefits. This creates incentives for firms to seek an orphan drug indication first, with a high price, and then to expand usage into other more common indications.⁽²³⁾

Unless the firm is able to segment the market effectively and to price discriminate effectively, prices will not reflect value (let alone marginal cost!) leading to inefficient outcomes. The firm will have every reason to promote the product for a low-value use if it is paid for the high-value use. Moreover, the uncertainty about the range of uses when multiple indications are possible will lead to challenges in setting an initial price. Negotiations around price may take a very long time as the insurer may fear that the product may be used chiefly in a low-value indication.

In addition, with a single price, the insurer is likely to impose restrictions on using the drug in patients for whom the benefit is likely to be modest. We see this in the complex prescribing guidelines initially put in place in the UK for sofosbuvir, with patients with different hepatitis genotypes and treatment experience being treated differently, even though all would have benefited from access to the drug. Those classes of patients with relatively low expected benefit were not treated in a timely way.

Problem 2. The second problem that arises because of multiple indications is that the incentives to invest in clinical trials for subsequent indications are distorted. As noted above, when there is a single price, insurers will tend to limit access to the drug to the patients with high-value indications. This outcome, however, has an impact on clinical trial design.

Suppose an innovator recognizes two patient groups that would benefit from treatment (high and low). Suppose that the monetary "value" of therapy in the high and low groups is respectively \$10 and \$4, and there are 100 patients in each. Suppose further that production costs per unit are \$1 and the cost of running a clinical trial in each group is \$100. If the innovator targets the high group only, it can price the product at \$10 and earn profits of \$800. If the innovator targets the average



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benefit (which was the economic model used by Gilead for sofosbuvir), pricing the product at \$7, the insurer may still approve the product only to treat the high group (since the benefit per patient in the low group is less than the price), resulting in profits of \$500. To include the low group, the product must be priced at only \$4, resulting in profits of \$400.

In this situation, the innovator's optimal strategy is to not even run a clinical trial for the low group, and hope that clinicians sometimes prescribe off-label to include them. This results in inefficiently low investment in clinical trials, as firms will find it more profitable to design trials that support use of the product only in high-value indications. If the firm could effectively price discriminate, the value of the product in the low-value group would be much higher than the costs of developing and supplying a product; but with a single price shared across both groups, supplying the low-value group reduces profits compared to targeting only the high-value group.

Unfortunately, this problem extends quite broadly, since it is very common for there to be a range of benefits obtained by patients, even within a single indication. Including low-value patients within the clinical trial will tend not only to weaken the case for market authorization but will reduce the price that the product can command if approved. In general, that leads to a bias towards fewer trials for lower-value indications and types of patients.

Problem 3. The current pricing model has led to a failure to invest in clinical trials on new indications once generic entry is imminent. In the US, as the threat of generic entry approaches, the number of new secondary indications for a medicine tends to decline substantially.⁽²⁴⁾ It is not hard to see why: the reward for performing clinical trials for a new indication is impaired because of the difficulty of benefiting from exclusivity. This has led to the evidently inefficient solution in the EU, in which a firm can win an extra year of regulatory data protection for all uses of a drug if the holder of the market authorisation can obtain an authorisation for one or more new therapeutic indications which bring a significant clinical benefit in comparison with existing therapies. That solution is inefficient because the size of the benefit (an extra year of marketing protection for all uses of the drug) is not proportional to the value of the new indication. Moreover, to earn this extra year of protection, the new indication must be added to the label within eight years after the product's approval, and there is no reward at all for a new indication following that.

ODRS as a solution. The ODRS, because it delinks the sales price from the reward to the innovator, can solve all three of the problems caused by multiple indications. First, it can solve the pricing problem by allowing the sales price to be the same across multiple indications, while having **separate rewards for different indications** or classes of patients. Thus, if there are two indications, one high- and one low-value, the ODRS requires only that the number of patients in each indication be tracked in order to provide the right reward amount.

Second, it can solve the problem of firms avoiding "low-value" indications. Because the reward amount for the high-value indication is not linked to the reward amount for the low-value indication, the firm need not worry that there will be any arbitrage or price reference. Thus, if the expected reward is greater than the clinical trial cost for the low-value indication alone, it will be profitable for the firm to invest in developing it. Referring to the numerical example above, under the ODRS, the firm would find it profitable to invest in clinical trials for both the high- and low-value groups – it would be able to earn \$800 from the high-value group and \$200 from the low-value



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group, net of clinical trial costs. In the language of economics, the ODRS allows for an **outcome that resembles perfect price discrimination**, which leads to the capture of more surplus.

Third, the ODRS can achieve better-tailored rewards for new indications for older drugs. For example, it would be possible to reward a firm for bringing new indications for the full 10-year period proposed for rewards, even if the new indication arrived after the product had first been introduced. Given that it is generally less costly to bring a new indication to market than a new chemical entity, a reasonable policy would be to modify the reward for sales of the product after generic entry. For example, the reward rate for sales of a product in its second indication in years 7-10 might be standard, but the reward rate for sales of the product in that indication in years 11-16 would be modified to only 25% of the standard reward. (In this case, the rewards would be paid even based on sales of the molecule by generic firms for the second indication.) The key here is that there is much more **flexibility** when rewarding a firm for value created through a separate payment rather than through high prices. By paying *fairly* for value, the ODRS could elicit much more investment into secondary indications. This is potentially of great therapeutic importance, since as noted above there is a significant lack of investment into investigation of secondary indications in older drugs.

It is worth emphasizing here that the possibility of multiple indications is one of the causes of delays in current HTA processes, as there is inevitably uncertainty about take-up of the product in different indications or patient groups. The ODRS, because it resolves the problems of appropriate compensation across different types of patients, also resolves the problems of delay in HTA processes.

3.5 THE ODRS CAN CORRECT PRICING FOR MARKETS WITH HISTORICALLY LOW PRICING

The problem. In countries that have consistently rejected HTA strictly based on QALYs, as is the case in Germany, there are sometimes inconsistencies in ICERs across therapeutic areas. In the German system, the HTA analysis focuses on whether a product maintains the ICER within a therapeutic area.(25) This allows for persistent differences between ICERs across therapeutic areas, and creates differential incentives for innovation.

The ODRS as a solution. The ODRS, without forcing a change to the entire system, would facilitate the payment of *fair* rewards to firms in currently undervalued therapeutic areas.

3.6 THE ODRS CAN CORRECT FOR DISTORTING EFFECTS OF VARIABLE PATENT PROTECTION

The problem. There is considerable variation in the duration of exclusivity achieved by different drugs. A study of 102 new molecular entities in the US found that while the exclusivity period of the median drug was 13.8 years, the drug at the 25th percentile had only 10.8 years before generic entry, while the drug at the 75th percentile enjoyed 14.8 years, or almost 40% more.(26) Differences across the tails of the distribution are even larger. Part of the reason for this is that there are significant differences in the length of clinical trials required for different types of drugs. This has significant effect on incentives. First, firms have strong, and possibly excessive, incentives to accelerate clinical trials to maximize the duration of exclusivity. Second, for classes of medicines that require long trials to demonstrate effectiveness, incentives are likely to be inadequate, potentially leading to underinvestment in some therapeutic areas.(27) One estimate put the annual



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lost life-years from misallocated cancer therapy research (away from early-stage therapies) at 900,000 annually in the US alone.(28)

The ODRS as a solution. The ODRS does not need to tie rewards to patent exclusivity. Because the firm makes essentially no profit from sales except through the reward paid for the health benefit achieved, exclusivity is not important. Even if generic entry into the molecule had already occurred, the innovator firm could be paid rewards based on the assessed health benefit from all sales of the molecule made by it and by generic competitors. This would eliminate the artificial penalty created by the patent system for therapies that require long clinical trials, since with the ODRS the innovator could anticipate rewards based on the health benefit for a full ten years. In effect, the ODRS could make rewards for innovation fairer across therapeutic categories and drugs with different anticipated clinical trial duration to reflect their real contribution towards health.

3.7. THE ODRS CAN OFFER FAIR PRICING FOR ORPHAN DRUGS

The problem. Drugs for rare diseases are another area where a single price is a poor reflection of social goals. While payers attempt to direct innovation through the expression of a cost-effectiveness threshold, orphan drugs are typically priced far above such a threshold, effectively undermining its credibility. Moreover, the high price, even if agreed by the insurer, can impose a challenging burden and undesirable incentives on local health authorities.

The ODRS as a solution. The **flexibility** of a reward system with price divorced from the payment for innovation could help to resolve this situation. With a reward system strictly applying a payment per QALY, of course, many orphan drugs would never be competitive. However, the ODRS could allow drugs to earn supplementary rewards based on disease prevalence. For example, there could be a modifier of 2x for diseases with prevalence below 1 in 10,000, and 5x for diseases with prevalence below 1 in 50,000. That would (partially) even up the rewards for diseases with differing prevalence and would provide **clarity for investors**. The implementation of modifiers is discussed in Section 4 below.

3.8 THE ODRS CAN SUPPORT EFFICIENT PROMOTION

The problem. Promotion is an important part of our pharmaceutical delivery system since it is often needed as a tool for prescriber and patient education. Nevertheless, there is widespread criticism of firms for engaging in promotion, since it is sometimes perceived as wasteful or, even worse, likely to lead to heavy use of a product by patients who obtain little or no benefit.

The ODRS as a solution. The ODRS would provide efficient incentives for promotional investment by firms. If the amount paid to the firm under the ODRS is strictly related to the health benefits, then the firm will have incentives to maximize the health benefits. Under the ODRS, the firm has no incentives to promote the product to patients who would systematically be expected to receive little or no benefit. If there is only a single price for the product regardless of the indication in which it is used, the firm would have the same incentives to promote it in all indications; in contrast, as described above, under the ODRS the firm would be more highly rewarded for higher value uses, leading to better targeting of promotional activities.



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4. IMPLEMENTATION DETAILS

This section provides additional information about implementation of the ODRS.

4.1 TIMING

The ODRS would be optional for patentees following the granting of market authorization: the firm could choose to proceed through the normal HTA processes or to make the product available under the ODRS. Firms would normally seek a prior understanding with the ODRS administration about how the product's health benefits would be evaluated, so that they could decide whether to choose that route. (In the alternative, the firm would be planning its submission for the HTA process.) If the ODRS were chosen, the firm would be required to set a price reflecting the costs of production and distribution only. (Getting this exactly right is not important as the revenues from sales would be deducted from the reward payment.) The low price would usually lead to an abbreviated process for determination of inclusion on insurance formularies. The firm would market and promote its product in the usual way. The reward payments would be made annually for the first 10 years after the product (or new indication) was introduced based on estimated incremental health benefits and costs each year.

4.2 SALES PRICE

The sales revenues should be deducted from the net reward paid to the innovator. This means that the cost per QALY would be independent of the sale price. Notably, this would make the supplier indifferent to the sales price, except for its possible influence on the volume of sales. That is, firms would have no incentive to seek a high sales price; if they did, it would not increase their total revenues. This would make it easier to set a price that would give prescribers, hospital and patients incentives perfectly aligned with the goal of optimising therapy.

4.3 HEALTH BENEFIT EVALUATION

Evaluation of the health benefits would be performed on an annual basis and would be based on the same data as would have been required in any HTA process, as well as the volume of sales that year in each indication, and, where relevant and available, other patient demographic data. (For example, there might be known or predictable differences in outcomes when used in patients aged over 90 compared to those in the clinical trials.) Where post-approval clinical trials are mandated by the regulatory authority, this data could also be incorporated into annual assessments. Notably, therefore, the kinds of data that are required are not substantially more onerous than is required for an HTA evaluation. Data on indications and patient demographics are increasingly available through existing administrative data systems.

The ODRS would reward based on incremental health benefits over the standard of care. The most plausible measure of health benefit is the QALY, as it has been most extensively used in practice. The weaknesses of QALYs are well known, and it would be important to allow for disease-specific measures that could be integrated with generic QALYs. Recognizing that QALY measures function poorly in many cases, the ODRS is not intended to be a universal tool, but an optional one. Thus, when the QALY would perform poorly in measuring the benefit attributable to a specific drug or even in a class of therapies, the ODRS need not be used. Similarly, it is recognized that for many



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drugs, there are supplementary benefits, such as patient convenience that are poorly captured by QALY measures, and so the ODRS might not be suitable. This makes *optionality* an essential design feature.

4.4 ADMINISTRATION

The ODRS administrator could be a component of a national health system, department of health, or the default insurer in a country, depending on the structure of the existing market. The net administrative costs would be small if insurance through the ODRS replaced insurance by other organizations for some drugs.

4.5 REWARD RATE

While the technical details differ from a single price system because the compensation for a drug is divided into two separate payments, the ODRS model would yield the same total payment to the firm as a single price system in which the price for the drug was set to achieve an ICER equal to r (the reward rate per incremental QALY), assuming an equal volume of sales.

Each drug would be eligible for an annual reward R according to

$$R_j = \sum_i r Q_{ji} m_{ji} - p_j q_j - \sum_i c_{ji}$$

where r indicates the reward rate, Q_{ji} represents the assessed QALYs in a year for the drug j and indication i , m_{ji} the relevant modifiers (such as whether it is an orphan drug indication), p_j the sales price for the drug, q_j the number of units sold and c_{ji} the net costs of using the therapy (excluding the sales revenues) compared to the relevant alternative. Net costs could be expected to be negative if the drug replaced an expensive therapy, in which case the reward to the innovator would be increased by the net savings.

Modifiers are an important feature of the reward mechanism, as they would allow for different levels of reward based on pre-specified criteria. While other modifiers are possible, plausible modifiers would include orphan drug status (with $m > 1$) and new indications for an existing drug (with $m < 1$).

The reward rate r would be set at the lower of the highest allowed reward rate per QALY \bar{r} (for example, £50,000) and the rate that would fully use the budget B :

$$r = \min \left(\bar{r}, \frac{B + \sum_j p_j q_j + \sum_i c_{ji}}{\sum_j \sum_i Q_{ji} m_{ji}} \right)$$

The essence of this is that the total rewards would never exceed the budget, while firms would obtain rewards based on the assessed health benefits of their products, and adjusted according to pre-agreed modifiers, with deductions made for their sales revenues and additions (deductions) made for net savings (incremental costs). The ODRS would seek cost-recovery from insurers when the net costs of implementing the drug j were negative (*i.e.*, there are cost savings from using drug j) and could compensate insurers when complementary costs of the therapy were positive (*e.g.*, use of drug j required additional hospital care).



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ODRS is by design a competitive market, such that if many products are included, it would drive the reward rate down. If the reward rate is perceived as too low by firms, then they will not seek to have their products included in it, so that the rewards should not fall to an unacceptable level. There would also be provisions allowing firms to exit ODRS if rewards fell below a pre-specified threshold.

4.6 BUDGET SIZE

How large should the budget for the ODRS be? A reasonable strategy would be to set the budget as a fraction of national insured expenditures, at least as a starting point. For example, if the ODRS budget were set at 20% of national pharmaceutical expenditures, one could anticipate that roughly 20% of drugs would shift to this reimbursement model. A rebalancing of the budget share of the ODRS could take place over time depending on assessments of its performance.

4.7 FUNDING

How should the financing for the ODRS be secured? The answer to this question depends entirely on what financing it is replacing. In the case of an integrated national health system as in England and Wales, the ODRS should be funded by the same body that provides existing drug insurance. In a mixed system, such as Germany's, the ODRS could be funded through the existing default insurer plus a levy on each insurer proportional to its non-ODRS spend. The levy should not be directly based on the actual share of ODRS claims originating from that insurer's customers, since that would in effect create 100% cost pass-through. However, in order to support efficient rewards, the ODRS should seek supplementary funding from insurers when the use of a ODRS product reduces their costs.

An important point to consider is that the ODRS appears to result in a different distribution of the sources of funding for drugs, since in the ODRS high prices do not fund innovation. It turns out, on closer inspection, that there is no significant change to the sources of funding compared to existing systems. Out-of-pocket payments for pharmaceuticals in OECD countries average only about 20%, with the other 80% coming from state or private insurance.⁽²⁹⁾ Since the ODRS's reward payments could be funded through a levy on existing insurance institutions, whether state or private, and the sales would be paid for in the ordinary course through a combination of existing insurance or out-of-pocket, the existing funding shares would be largely preserved.

Because the ODRS acts as a backstop in negotiations with the insurer, the budget is very important. The budget will help to determine the reward rate, which will increase if the budget increases (subject to a maximum of \bar{r}). If the budget is too high, then firms will find negotiation with the insurer pointless. If too low, the reward rate will offer little protection to firms. Ultimately the budget should be set so that the reward rate is similar to the typical effective payment per QALY in the absence of the ODRS. This would mean that it creates an option when negotiations about prospective value are unfruitful.

4.8 INITIATION

One challenge for initiating the ODRS is that firms would likely be hesitant to commit to the system given uncertainty about the reward rate. One way to address this is to fix the reward rate for the



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first products in the system so that predictable payments would use up a maximum of e.g. 70% of the budget, and to allow the remaining budget to be divided competitively. Over time, the share of the budget allocated to fixed rewards could be reduced to zero. Firms would be more comfortable with the ODRS if they had observed a stable reward rate.

5. WHAT PRODUCTS WOULD SUIT THE ODRS?

Since the ODRS is not intended to be universal, it is important to consider what kinds of products would be selected for it. Of course, in general, the option would be left up to the patentee, so at most one can identify what are the incentives to enter this system. What should be clear, based on the discussion in Sections 3 and 4, is that some types of products would be a poor match: for example, products that mainly increased patient convenience without conferring meaningful health benefits would not be adequately rewarded under the ODRS.

Products that would particularly benefit from the ODRS are those for which there is considerable uncertainty about likely effects at the time of market introduction. This would certainly be the case given that when there is significant uncertainty, the HTA and price negotiation processes are likely to be slow and entry could be delayed.

Products in therapeutic areas where long clinical trials are required might find the ODRS the only route to commercial feasibility. Similarly, the ODRS model for reimbursement of late-arriving secondary indications would likely be attractive. Generally, products in classes with traditionally low reimbursement but meaningful health benefits may find the ODRS appealing.

In other circumstances, the ODRS might serve as a backstop in case of negotiation breakdown, enabling an innovator to hold firm on price, whether or not it eventually chose to be reimbursed under the ODRS.

6. INTERNATIONAL ASPECTS

A key feature of the ODRS is that it can be extended internationally. One of the failures of our current system is that prices are often quite similar across countries with very different abilities to pay. This is not due to the underlying costs of manufacture, which are usually very low compared to the price, but to **concerns around arbitrage and external price referencing**. The inability to fully price-discriminate internationally is bad for patients in poorer countries and for the profits of innovators. (It may, under certain circumstances, be good for payers in wealthy countries.) Just within Europe, charging similar prices in Romania and Germany may be difficult to avoid given EU regulations and the short distances involved, but does not respect the very different financial capacities of the countries. This problem could be entirely solved with the ODRS, as the price in both countries would be equalized at a low level, with each country paying a reward to the patentee based on assessed health benefits. The level of the reward payment, however, might be very different based on the financial capacity of the country.



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A **global ODRS** would involve a single pool, with the reward allocation based on health benefits across all participating countries summed without regard to the patient's country. This would transform the incentives to invest in diseases that are chiefly prevalent among very poor people.

As is well known, there is relatively little R&D focused on the **diseases of poverty**, presumably because poor people's effective demand is weak. The lack of attention to neglected diseases by "big pharma" is shared by governments, which tend to focus their research spending on the same set of diseases.⁽³⁰⁾ This is presumably because their primary focus is on the diseases that affect their own populations. A reward fund that rewarded health gains anywhere would presumably be particularly attractive for drugs with large potential therapeutic benefits that cannot obtain attractive commercial rewards through the price system. Such drugs are above all drugs that primarily address the needs of patients in low-income countries.

GSK's recent "success" in a malaria vaccine, Mosquirix, is a good example of the problems of the current system. GSK has been working on Mosquirix for over 30 years. It has now earned a contract with UNICEF for supply of [18 million doses over three years for \\$170m](#), or less than \$60m a year. This is, perhaps, enough to cover its manufacturing costs, but will not even begin to address the 30 years of development costs. Evidently, the price system is not designed to reward firms for developing drug products that are primarily used by the poor, which is deeply problematic. Many of the most deadly diseases in the world – such as HIV, tuberculosis, and malaria – disproportionately burden low-income countries. Altruism from large companies is not a sustainable solution, nor will it ever result in the scale of investment that is required to address the neglected diseases of the world.

The failure to invest in these diseases can come back to bite the rich world: high-income countries have spent billions of dollars over the past few years to mitigate the risks of zika, ebola, and monkeypox, all diseases that were first present in low-income countries and which have threatened to spread in high-income countries. A reward fund which recognized the value of improving the health of people regardless of their country of residence could provide the resources and incentives for companies to address such infectious diseases before they spread. If the "next" covid arrives from untreated infections in a low-income country, as seems most likely, the self-interest of the rich countries will be truly to blame.

The world has already seen a truly devastating pandemic evolve in low-income countries over many years, and eventually spread to become a global disaster: the ancestral strain of HIV-1 was present in humans in Central Africa from at least the 1930s, and attracted no medical interest from wealthy countries at the time. It seems to have begun to spread internationally only starting in the 1960s.^(31,32) To be sure, the ability to diagnose and track diseases has improved enormously since the mid-twentieth century, but it isn't clear that the world has really learned much from its experience with HIV/AIDS. Other infectious diseases continue to circulate in low-income countries, with the continuous potential of mutating into more infectious variants and putting the entire world at risk. Indeed, the monkeypox crisis exactly mirrors this situation. Other previous episodes classified as "Public Health Emergencies of International Concern" such as the zika virus and Ebola show that there is much more interest in infectious disease threats once they spread into high-income countries.



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With an international ODRS, which could function along the lines of the Advance Market Commitment or the proposed Health Impact Fund, it would be possible to support the development of new medicines for diseases that currently lack much commercial pull. And as an important corollary, such a mechanism would **drive not only innovation but also delivery** since the amounts paid out would depend on whether people were actually treated (or vaccinated).

A global ODRS could be separate from national ones, recognizing that there might be different goals and levels of payment. However, the principles would remain the same: access achieved through efficient, marginal-cost pricing; innovation and investment in product delivery supported through rewards based on assessed health benefits; and optional participation by pharmaceutical innovators.

In the case of an ODRS targeting neglected diseases, it would be most appropriate for the funding to come from high-income country governments, perhaps as a contribution towards their development assistance commitments.

6.1 HOW THE ODRS DIFFERS FROM THE HEALTH IMPACT FUND

According to <https://healthimpactfund.org>, the proposed Health Impact Fund targets innovation into “diseases concentrated among the poor”, unlike the ODRS, which is designed as a general complement to existing systems of insurance. However, the general theme of having a two-part price in which the price to the patient is delinked from the reward to the pharmaceutical innovator is similar, as with other types of mechanisms such as Advanced Market Commitments, the UK’s Antibiotic Subscription Pilot, or Australia’s contract for direct-acting antivirals. The ODRS is unique as a fully conceived complement to existing structures of insurance in high-income countries. Moreover, the ODRS is proposed as a solution within a country, with a different funding structure (based on existing insurance) and different reward mechanism (fully accounting for cost differences).

7. ODRS IMPLEMENTATION CHALLENGES

The ODRS depends on the measurement of health benefits to operate effectively. In some countries, this would necessitate additional investments in health systems to estimate benefits. In high-income countries, administrative records are already adequate to identify patient characteristics and indications (most of the time). In developing countries, tracking usage is certainly more challenging, and so the ODRS would require more investment to work well. Estimating health benefits would often be contentious; clear contracts and an expeditious appeals process would be needed.

As discussed above, the ODRS depends on the availability of an adequate, stable budget. If the budget is too low, then it offers little to innovators; it seems unlikely that it would ever be too high. The price per QALY needs to account for the willingness to pay for health gains in each jurisdiction in which it operates.

The ODRS could be vulnerable to systematic underfunding. The escape valve for this is that firms would not be required to use it. Of course, if the government underfunded the reward system and



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also refused to pay high prices for drugs outside the reward system, that would undermine incentives for innovation. The ODRS would also need some degree of cooperation with national or private insurers to operate optimally. Achieving such cooperation would undoubtedly be challenging in some countries.

8. SUMMARY

Our current pharmaceutical market is undermined by trying to use a single tool – price – to achieve multiple objectives. This creates unproductive conflict between patients and industry, rather than a shared focus on the question of how to maximise the development of drugs for the benefit of population health. By offering an option in which price is used to support access, and separate payments are used to support innovation, the ODRS can improve outcomes in the pharmaceutical market for patients, payers, and industry. The ODRS can help to minimise opportunism by insurers by creating a transparent, competitive model for innovation rewards; it can help to accelerate access to new therapies, benefiting both patients and industry; it can create a better pricing structure for multi-indication drugs and support clinical trials for secondary indications.

In summary, the ODRS offers a way to make pharmaceutical prices fairer while enabling the innovation our society urgently needs.



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