

SHARING THE BURDEN

Could risk-sharing change the way we pay
for healthcare?



Sharing the Burden: Could risk-sharing change the way we pay for healthcare?

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Executive Summary

Risk-sharing is a relatively new concept in the field of healthcare policy. As such, it is subject to confusion and misunderstanding, not only in terms of terminology but also in terms of substance. Different countries adopt and apply different forms of risk-sharing models and mechanisms. It is because of this confusion that the Stockholm Network is now seeking to demystify the concept of risk-sharing and to explore it in a more systematic way.

Risk-sharing needs to be understood as part of a broader policy reaction to the sustained historical growth in health care expenditure. As health budgets have progressively grown and health care itself has become more expensive, health policymakers have had little choice but to try to implement various mechanisms to stem this rise so as to make more efficient use of their existing resources.

There is an impression among policymakers that pharmaceuticals are an important reason for ongoing rises in health care expenditure. However, this assumption ignores the fact that around 80% of health care spending is actually spent on other costs. While these other costs have risen year on year, pharmaceutical spending as a percentage of total health expenditure is actually decreasing in many OECD countries. Although this is not an attempt to suggest that pharmaceutical spending does not have an important impact on overall health spending, it is only reasonable to view spending on medicines in the context of overall healthcare costs.

Risk Sharing

In a general sense, the concept of risk-sharing may be defined as the process by which two parties or more agree to share the risks associated with achieving a certain outcome. To this extent the parties should have a mutual interest in achieving that outcome and should agree on the manner in which they define the risk and deal with it throughout this process. In the commercial and financial worlds, risk-sharing is linked mainly to the issue of cost, i.e. the costs that may or may not be incurred by the parties by taking the risk of trying to reach a mutual outcome.

Among the many schemes examined in this paper, it seems unclear if the objectives generally sought after in risk-sharing agreements are actually being achieved, including controlling costs, increasing patient access to medicines in a timely manner and improving the incentives for innovation. Even in examples where the objectives have been achieved, it appears that in many cases the process has not necessarily been worth the cost and time involved.

As with many cost-containment measures, it seems that the theory is much more attractive than the practice, with a wide variation in outcomes across and within different healthcare systems. Risk-sharing schemes are certainly still in their infancy and the inconsistency of success is testament to this and to the need for further experimentation. The only guarantee currently seems to be that the cost of administering, negotiating and managing such schemes is likely to remain high.

The pitfalls of risk-sharing schemes have been laid bare in this study: time-consuming negotiations, costly administration, difficulty in assessing success and over-complicated arrangements are just a few. However, in many cases the failure of the scheme has not necessarily been down to an inadequacy of the pharmaceutical product itself, but rather a "malfunction" in the design of the risk-sharing agreement. As a result, it is usually

very difficult to predict if a risk-sharing scheme will work or whether it will fail, allowing for inconsistent results. There is, as yet, no gold standard for risk-sharing agreements, nor is there ever likely to be one.

One of the main reasons why risk-sharing schemes have been so difficult to implement, despite the fundamental consensus as to why they are important, is because they have been used for motives aside from purely providing patient access. In many instances, payers have seen risk-sharing as a tool for bringing down health care budgets, which many policymakers maintain is due to high spending on pharmaceuticals. As such, risk-sharing is not an innovative concept but rather a continuation of a cost-containment approach seen in pricing and reimbursement systems more generally.

However, if policymakers see risk-sharing as a “golden bullet” for driving down costs, they are mistaken. Using risk-sharing as a convenient fig leaf for cutting pharmaceutical prices undermines the potential for creating a true concept of risk-sharing, whereby payers and manufacturers work together to distribute risk between them for the public good. Such a concept would rightly acknowledge the constraints on both payers, who have finite resources to spend on healthcare, and manufacturers, who must recoup the investments they have made to bring the product to market.

Payers should acknowledge that risk-sharing agreements need to genuinely factor in the efforts and risks associated with the development of new medicines, as well as the regulatory, financial and commercial risk of managing these medicines once they have reached the market. Manufacturers need to acknowledge the fact that risk-sharing agreements may require them to share the burden of providing more information about the efficacy of their medicines and, at times, even to share the burden of financing these medicines.

However, most importantly, risk-sharing agreements should reflect a true commitment to serve the needs of patients, to allow for greater individual choice, while securing the most effective methods of treatments. This means that the risk may be at the expense of payers, or manufacturers or both - but never at the expense of patients.

Policy recommendations

In order to protect this principle a number of recommendations are provided below.

- We need to accept that risk-sharing is still in its infancy and that current experiences are by no means a basis for widespread use. When drugs are rejected for reimbursement, a risk-sharing scheme can act as a band-aid over the damage, yet this is not a sustainable system for the future.
- A pre-condition for the creation of an effective risk-sharing agreement is to understand what were the specific reasons for including, or not including, a certain drug for reimbursement. These reasons provide the basis upon which risk-sharing arrangements may be created.
- Risk-sharing schemes need to adequately address both price and performance concerns. Current examples seem to suggest that the former is dictating the mechanisms by which risk-sharing schemes work and that, to this extent, risk sharing agreements aim to control the issue of cost rather than to deal with the issue of risk.
- Risk-sharing agreements are a means to an end. If the primary intention is providing greater access to the best available treatments within finite budgetary frameworks then risk-sharing should be considered as part of a wide range of policies aimed at serving this objective.

Introduction

Risk-sharing is a relatively new concept in the field of healthcare policy. As such, it is subject to confusion and misunderstanding, not only in terms of terminology but also in terms of substance.

As will be discussed in this paper, different countries adopt and apply different forms of risk-sharing models and mechanisms. Some countries consider risk-sharing as another tool for controlling public expenditure on medicines and treatments, while other countries adopt more substantive risk-sharing arrangements dealing with information, outcomes research, financing, compliance and so on. It is because of this confusion that the Stockholm Network is now seeking to demystify the concept of risk-sharing and to explore it in a more systematic way.

Accordingly, this paper will examine and compare risk-sharing schemes in the following five countries: Australia, Germany, Italy, the United Kingdom, and the United States. As these countries have different types of health systems – ranging from a mix of private and public providers as well as payers in Australia and the US to more monolithic public systems such as the UK National Health Service – the sample should provide greater insight into the use of risk-sharing than if the health systems had been very similar.

The paper has been divided up into three main sections: The first section will aim to set the scene for a discussion on risk-sharing, outlining what risk-sharing is and how different risk-sharing schemes work in practice. In doing so, the paper discusses the problem that ever-increasing healthcare budgets pose to policymakers, identifying the main reason for the rise of risk-sharing. The political reality that currently prevails – especially given the state of the world economy - means that any pragmatic study of risk-sharing must first take account of the need to bring down health care costs.

The second section provides most of the substance of the paper, by examining risk-sharing in practice in Australia, Germany, Italy, the UK, and the US. This section moves away from analysing risk-sharing as a concept and considers 27 risk-sharing schemes agreed in the “real world”. Each country is analysed in a way that allows for an understanding of the environment for risk-sharing both now and in the future.

Finally, the paper concludes its findings on risk-sharing and provides policy recommendations on how risk-sharing can be improved – primarily, arguing that we should move towards a more mature set of models which really seek to share long-term risk rather than simply to control and reduce short-term costs.

Section I: Introducing and defining risk-sharing

Risk-sharing needs to be understood as part of a broader policy reaction to the sustained historical growth in health care expenditure. As health budgets have progressively grown and health care itself has become more expensive, health policymakers have had little choice but to try to implement various mechanisms to stem this rise so as to make more efficient use of their existing resources. Over the past 40 years, public and private spending on health care within the OECD has increased by a factor of between 2 and 3. In 1960, none of the twelve countries for which the OECD has statistics spent more than 5.4% of their GDP on health care.¹ Almost five decades later, none of the OECD's 30 member countries actually spend *less* than 5.4%.² In 2009, OECD countries were on average spending 8.9% of GDP on health care.³

The five countries sampled for this study are no exception to this. Indeed, they have all seen substantial rises in their national health expenditure. Table 1 shows the historical rises in health care spending between 1970 and 1995, whilst table 2 shows more recent rises between 1995 and 2008. Both show the figures as a percentage of GDP but also per capita, measured in US\$ purchasing power parities, to show both the relative and real terms rises in health spending.

Table 1: Total health care expenditures, as a percent of GDP (left) and per capita (right), in sample countries between 1970 and 1997

	Australia		Germany		Italy		UK		US	
1970	5.7%	\$207	6.3%	\$224	5.2%	\$154	4.5%	\$144	7.3%	\$357
1980	7.3%	\$663	8.8%	\$824	7.0%	\$579	5.6%	\$444	9.1%	\$1086
1990	8.2%	\$1320	8.7%	\$1602	8.1%	\$1321	6.0%	\$955	12.6%	\$2798
1995	8.4%	\$1778	10.4%	\$2178	7.7%	\$1534	6.9%	\$1253	14.1%	\$3776

Table 2: Total health care expenditures, as a percent of GDP (left) and per capita (right), in sample countries between 1996 and 2008

	Australia		Germany		Italy		UK		US	
1996	7.4%	\$1707	10.4%	\$2392	7.4%	\$1609	6.8%	\$1433	13.5%	\$3900
1998	7.6%	\$1939	10.2%	\$2480	7.7%	\$1833	6.7%	\$1559	13.4%	\$4236
2000	8.0%	\$2266	10.3%	\$2669	8.1%	\$2064	7.0%	\$1837	13.4%	\$4703
2002	8.4%	\$2559	10.6%	\$2934	8.3%	\$2235	7.6%	\$2192	14.8%	\$5453
2004	8.5%	\$2870	10.6%	\$3161	8.7%	\$2372	8.0%	\$2548	15.4%	\$6196
2006	8.5%	\$3168	10.5%	\$3471	9.0%	\$2662	8.5%	\$2884	15.5%	\$6931
2008	N/A	N/A	10.5%	\$3737	9.1%	\$2870	8.7%	\$3129	16.0%	\$7538

Source: OECD⁴

¹ OECD.Stat, Health Expenditure 1960. See <http://stats.oecd.org/>

² *Ibid.* Health Expenditure 2007.

³ OECD, *Health at a Glance 2009*. See <http://www.oecd.org/health/healthataglance>

⁴ Huber, M, *Health Expenditure Trends in OECD Countries - 1970-1997*. See <http://www2.cms.gov/HealthCareFinancingReview/Downloads/99winterpg99.pdf>

Out of the five countries studied in this paper, the smallest increase in health spending between 1970 and 2008, as a percentage of GDP, was seen in Australia, which saw a 49% increase. The largest over this 38-year period was seen in the US, which increased by 113%. In real terms, the average percentage increase of per capita spending in all the five countries in this study from 1970 to 2008 was 1,769%. This growth unsurprisingly alarms policymakers, particularly when you consider it in comparison to GDP growth. Table 3 shows recent statistics relating to real annual growth in per capita health care spending alongside real annual growth in per capita GDP, between 2000 and 2008. These figures show that in all the countries in this study, as well as in every single country in the OECD, health spending per capita grew faster than GDP, highlighting how unsustainable health spending has become.

Table 3: Real annual growth in per capita health spending (left) and GDP (right) between 2000 and 2008

	Real annual growth in per capita health spending between 2000 and 2008 (%)	Real annual growth in per capita GDP between 2000 and 2008 (%)
Australia	2.9	2.1
Germany	1.6	1.2
Italy	1.9	0.4
UK	4.6	2.0
US	3.4	1.2

Source: OECD⁵

Policymakers have often focused on stemming the growth in health spending by cost-control measures relating to pharmaceutical spending. This is particularly true for countries where the public sector plays a large role in the provision and/or reimbursement of medicines. Over the years, pharmaceutical cost-containment measures have come to include: the introduction of co-payments for pharmaceutical dispensation; profit controls on medical and pharmaceutical products; reference pricing and international comparisons of medicines; and the development, and use, of health technology assessment (HTA) and cost effectiveness comparisons. More recently, some countries have been more forthright in their attempts to lower pharmaceutical expenditure by instigating arbitrary cuts in pharmaceutical prices, for example Greece, which has some of the cheapest drugs in Europe. In May 2010, as its economy faltered, Greece announced cuts in medicine prices to drug wholesalers of an average of 25 per cent.⁶ Other countries with similar intentions are Germany, which announced increased rebates on branded medicines of between 6% and 16%, and Spain, which slashed prices by as much as 23%.

The paper will now briefly discuss some of these attempts at containing pharmaceutical costs in order to provide the context within which risk-sharing is being considered. It will then go on to define risk-sharing. We begin by looking at the two main mechanisms whereby health policymakers influence the price of medicines: pricing and reimbursement policies.

⁵ OECD, *Health Data 2010*. See http://www.oecd.org/document/11/0,3343,en_21571361_44315115_45549771_1_1_1_1,00.html

⁶ "Novo rejects Greek call to cut drug prices", *Financial Times*, 1 June 2010. See <http://www.ft.com/cms/s/0/19b6d006-6d06-11df-921a-00144feab49a.html>

1.1 Pricing and reimbursement policies – an outline of common practices

While pricing and reimbursement policies can differ substantially in how they have been formulated and implemented across the OECD, there are broad similarities in the kinds of overall strategies that are used. To begin with it is worth noting that the overall shape of a health system impacts on how pricing and reimbursement policies are set and, perhaps most importantly, on who sets them.

Broadly speaking, and apart from the patients they serve, health systems consist of three main actors: payers, providers and regulators. In some systems these roles are filled by a mixture of private and public institutions. For example, in the US most providers are from the private sector. Doctors' practices, hospitals and care homes are usually, but not exclusively, privately run. Similarly, a large proportion of payers – which in the case of the US are usually private health insurers – are also in the private sector. This is not to say that the public sector does not play a significant role in the US; on the contrary, both the federal government and individual state governments, chiefly through the Medicare and Medicaid programmes, are substantial health payers and influence health policy in a number of ways. Still, the major role the private sector plays in American health care is almost unique within the OECD. Indeed, in other countries the situation is very different. In the UK, for instance, the state both provides and pays for the overwhelming majority of care. Most countries run a mixed system with the emphasis usually being on the state or a state-linked institution, such as a social insurance fund, as a payer for care. Regulators, on the other hand, are invariably part of the public sector. However, here too it is important to note over which areas of health policy regulators have jurisdiction. For example, in most European countries, as well as Australia, decisions relating to the pricing and reimbursement of medicines are taken by some national, state or state-linked institution. Conversely, in the US, pricing and reimbursement decisions are taken by individual health payers, regardless of whether they are public or private.

The most direct form of controlling prices for countries with a national framework for price regulation is that of statutory pricing. Health authorities set and directly control the price for a medicine either through setting the ex-factory price, the wholesale price or the pharmacy retail price. This type of price control is quite common within Europe. A major study of pricing and reimbursement policies within the EU, funded by the European Commission and the Austrian federal government, found that 18 EU and European countries had some form of direct price controls in place.⁷ In some countries, such as Italy and France, prices were set in negotiation with the pharmaceutical industry, but in most cases prices were set directly by the relevant pricing authority.

While not as direct as price or profit controls, reimbursement lists and formularies are another powerful tool that health bodies use to regulate the price of pharmaceuticals. As the name suggests, reimbursement lists are simply a physical listing of which drugs are to be reimbursed and at what price. Pharmaceutical formularies are also lists of what medicines and treatments are to be prescribed and used for specific illnesses and diseases.⁸ They are used frequently by hospitals, health care trusts, health insurers, and any final payer of health care services.

Formularies can either be closed or open. Closed formulary systems restrict drugs provided to those on the list. Prescribing physicians are thus left with a limited set of medicines from which to choose. Open formulary

⁷ Vogler, S. *Pharmaceutical Pricing and Reimbursement Information* (2008), pp. XVI-XVII.

⁸ American Medical Association (AMA), "Impact of Drug Formularies and Therapeutic Interchange on Health Outcomes: Report 2 of the Council on Scientific Affairs", 2004, <http://www.ama-assn.org/ama/no-index/about-ama/13675.shtml>.

systems will cover drugs that are not labelled as preferred, that is, those drugs that are not on the formulary list. Open lists usually include an incentive-based system, in which formularies are tiered, with varying levels of co-payments. Crucially, lists and formularies are used by both private and public health bodies. Private health insurers make extensive use of drug formularies and often used tiered formularies which seek to incentivise choices within the lists of preferred or generic drugs by charging more for non-preferred drugs. For instance, in the US, many employer-based health insurers⁹ have three-tiered formularies. Under these formularies the three most common tiers are: generic drugs, which have the lowest co-payment; preferred branded drugs, which have a mid level co-payment; and non-preferred branded drugs, which have the highest co-payment.¹⁰ Even large public payers, such as the US Medicare programme, operate a system of tiered co-payments for their own drug plans.¹¹ Within the EU, reimbursement lists are very common. Virtually all member states employ reimbursement lists or national formularies, either positive or negative, that is, describing either which medicines are to be reimbursed (a positive list) or those that are not to be reimbursed (a negative list).

In addition, when setting prices and reimbursement levels for medicines, health authorities often compare their prices to a basket of domestic prices (internal reference pricing) and/or international prices (external reference pricing). As the name suggests, international comparisons compare and set a price for a medicine or a reimbursement level based on the prices and reimbursement levels in other countries. In Greece, for example, the price for branded pharmaceutical products is the average of the three lowest prices among EU Member States. In Italy, for medicines where generics are available, prices are set at the lowest medicine price of all the EU Member States, while for medicines where no generics are available, prices are set at the average cost of all the EU Member States. With internal or domestic reference pricing, prices and reimbursement amounts are set in comparison to a basket of what is deemed to be similar medicines. Similarity is determined either by a traditional comparison of the active substance employed by the medicine or, in a new departure, by therapeutic similarity.¹² Most countries base their comparisons on active substances, but Germany, the Netherlands and the Czech Republic have begun using comparisons of therapeutic similarity.^{13,14}

1.2 New departures – HTA and risk-sharing

Many OECD countries, including Australia, Germany, and the UK, have also moved into the field of HTA. The Stockholm Network has written extensively about the use of HTA and even has its own HTA programme¹⁵, therefore this paper will only go over it briefly. HTA is an evaluation of new medicinal technologies and procedures, including pharmaceutical treatments, which usually, though not always, involves a cost-benefit analysis. Based on HTA assessments, health officials make recommendations on whether or not a medicine should be reimbursed and at what percentage. These recommendations can either be binding, i.e. they

⁹ These insurers are the most common in the US with almost 6 of every 10 Americans receiving their health insurance through their employers or the employers of their spouses or family.

¹⁰ AMA (2004).

¹¹ Kaiser Family Foundation, "The Medicare Prescription Drug Benefit Fact Sheet", November 2009, <http://www.kff.org/medicare/upload/7044-10.pdf>

¹² Therapeutic similarity is a relatively new way of referencing and has widened the internal reference pricing to medicines that do not necessarily employ the same active substance or ingredient. It largely leaves it up to the medical and/or reimbursement authority to decide what is considered to be of therapeutic equivalence.

¹³ *Ibid.*

¹⁴ Stockholm Network, *Patient safety and comfort: the challenges of switching medicines*, 2010. See http://www.stockholm-network.org/downloads/publications/Patient_Safety_and_Comfort_The_Challenges_of_Switching.pdf.

¹⁵ Information on the Stockholm Network HTA programme and publications can be found at <http://www.stockholm-network.org/Conferences-and-Programmes/Health-and-Welfare/HTA>.

become actually policy, or merely act as guidance to the relevant reimbursement and health authorities. From the countries in our sample, the UK, Germany and Australia have the most sophisticated and advanced forms of HTA. In the UK, the National Institute for Health and Clinical Excellence (NICE) is viewed as a pioneer in HTA and its findings are a crucial policy tool for health policymakers. In Australia, HTA is mainly carried out by two national level government entities: the Medical Services Advisory Committee (MSAC) and the Pharmaceutical Benefits Advisory Committee (PBAC). Other countries such as France, Sweden and the Netherlands are also increasingly using HTA.

HTA is especially significant to this study because it is often a cost effectiveness assessment that triggers the consideration of risk-sharing assessments. As this paper will show, many of the risk-sharing schemes in place have been a reaction to assessments that have deemed a pharmaceutical as not being sufficiently effective in regards to its costs. Whilst it is difficult to judge whether risk-sharing would exist without HTA, it is certainly the case that the two are closely linked.

1.3 Pharmaceutical spending in perspective

What the above points to is an impression that policymakers see pharmaceuticals as an important reason for ongoing rises in health care expenditure. However, as this paper makes clear this assumption ignores the fact that around 80% of health care spending is actually spent on other costs. While these other costs have risen year on year, pharmaceutical spending as a percentage of total health expenditure is actually decreasing in many OECD countries. In fact, general conclusions from statistics relating to pharmaceutical spending suggest a diverse picture as to the growth and size of such expenses. Historical OECD figures show that in Germany, for example, pharmaceutical spending, as a percentage of total health spending, was 16.2% in 1970 and had decreased to 15.1% by 2005. France has also seen a dramatic drop from 23.8% in 1970 to 18.5% in 2005. Only two major EU countries, Sweden and Portugal, saw dramatic rises in the amount of health spending going to pharmaceuticals from 1970 and 2005.

In most OECD countries, pharmaceutical expenditure does indeed represent a sizeable part of the overall health budget and, on average, pharmaceutical spending represents 1.5% of GDP in the OECD¹⁶. Yet, table four shows the average annual increase in pharmaceutical spending, as a percentage of total health spending for two different time periods. It shows that in four of the five countries in this survey pharmaceutical spending, as a percentage of total health spending, grew more slowly between 1999 and 2008, than it did in the previous period between 1990 and 1999. In fact, in Italy and the UK, on average, the percentage of health spending on pharmaceuticals each year decreased between 1999 and 2008. Only in Germany did pharmaceutical spending, as a percentage of health spending, increase, on average, year on year. Even when we consider the annual growth in real terms pharmaceutical spending, we see that the rate at which spending on pharmaceuticals is growing year on year is actually decreasing.¹⁷

¹⁶ OECD, *Health at a Glance 2009*, p167.

¹⁷ *Ibid.*

Table 4: Average annual increase of pharmaceutical spending, as a percentage of total spending on health

	Average annual increase in pharmaceutical spending as a percentage of total health spending between 1990 and 1999	Average annual increase in pharmaceutical spending as a percentage of total health spending between 1999 and 2008
Australia	3.77 %	0.51 %
Germany	-1.13 %	1.31 %
Italy	0.99 %	-2.00 %
UK	2.37 %	-2.19 %
US	2.24 %	1.11 %

Source: OECD¹⁸

Although this is not an attempt to suggest that pharmaceutical spending does not have an important impact on overall health spending, it is only reasonable to view spending on medicines in the context of overall healthcare costs. What these figures show is that it should not be taken as a given that the policymaker's main focus for cutting health care spending should be on pharmaceuticals. Instead, moves to curtail growing health budgets should target a variety of costs and liabilities, such as the need for health system reform. Perhaps it is also taking into account the hard-to-measures savings that may come from successful pharmaceutical treatment? Last but not least, it is also worth noting that not all spending on pharmaceuticals comes from public budgets, even in countries with state-led health care systems. On average in the OECD, 40% of pharmaceutical spending is paid for by private sources, whilst in countries, such as the US, the figure is unsurprisingly higher at 69%.

Nevertheless, in the pursuit of lower pharmaceutical spending, policymakers are looking to change the way in which products are priced and reimbursed, which is why they are now turning their attention to the concept of risk-sharing. Although a popular and much talked about idea in policy circles and among health care professionals, risk-sharing has not been thoroughly conceptualised or defined for a wider audience. Of equal importance, risk-sharing has not been subject to adequate practical and empirical analysis. It is crucial that health policymakers and industry professionals have a much better understanding of what the actual real-world results of risk-sharing schemes are in those countries where they have been implemented. Do existing risk-sharing schemes accurately reflect a true sharing of risk between public reimbursement bodies and pharmaceutical manufacturers or are they more akin to other models of cost-containment such as price and profit controls?

1.4 Risk-sharing for Medicines

In a general sense, the concept of risk-sharing may be defined as the process by which two parties or more agree to share the risks associated with achieving a certain outcome. To this extent the parties should have a mutual interest in achieving that outcome and should agree on the manner in which they define the risk and deal with it throughout this process. In the commercial and financial worlds, risk-sharing is linked mainly to the issue of cost, i.e. the costs that may or may not be incurred by the parties by taking the risk of trying to reach a mutual outcome.

¹⁸ Original statistics for pharmaceutical spending, as a percentage of health spending, from OECD *Health Data 2010* – actual figures attained by calculating the annual growth of each year and then determining the average growth for the years shown.

Imagine, for example, that a company manufactures a toy that they believe will be the number one seller at Christmas. This company may take this toy and attempt to encourage shops to sell it in their stores by showing them reams of market data that suggests that children are going to want it this year. The shop may still be uncertain about committing to a product relying purely on market data. If the manufacturer fails to convince the shop to buy the product it will have run the risk of spending its time and money developing and manufacturing a toy that could not be sold. On the other hand if the shop agrees to sell the toy and nobody buys it, the shop too will have run the risk of spending its time and money on an unsuccessful product. Therefore, in this instance, there may be a mutually beneficial arrangement that the two parties can agree on that would help them to share their respective risks in order to be able to manufacture and sell this product. These mechanisms can vary from different types of discounts, specific promotions, agreeing on a certain design and prototypes of these toys, etc.

Medicines, of course, are unique products. While toys are ultimately a matter of preference, individual taste, and contemporary fashions ("flavour of the month") medicines are not, since they aim to serve one of our most basic needs. There is a huge difference between dealing with risks that are associated with personal preference and dealing with risks that are associated with public needs. Moreover, since in many different countries a large portion of the supply and financing of medicines is provided by the state, the relationship between suppliers (pharmaceutical companies), payers (be it the government directly or dedicated organizations such as insurers or sick funds etc) and users (the public and patients) is ultimately much more complex. Generally speaking, one can identify three major risks in this context:

From the perspective of pharmaceutical companies there is clinical and commercial risk. Clinical risks focus on the ability of pharmaceutical companies to develop and bring a new medicine to the market. Current statistics suggest that during the long process of research and development (today estimated at 14 years and at \$1.4 billion) only 1 out of 5000 molecules will reach the final phase of being successfully approved by health authorities as a safe and effective medicine for public use.¹⁹ Commercial risks concern the ability of these companies to secure a "return on investment" on their products. Again, here statistics suggest that only one out of three products will recoup its investments costs.

For the payer, the risk is about allocating public monies in order to finance the above medicines. Since the payers do not have the means to finance all products, they will be unable to fulfil their obligation to their patients to provide access to the best medical treatments. The question is therefore how to allocate public money in order to get the best results for the public in terms of the medicines that are being financed.

Finally, for the patient there is the risk that decisions that are made on the basis of the public as a whole may come at the expense of the needs of the individual patient(s). Here the most typical example is that a certain medicine may not be considered to be "sufficiently" cost-effective by the payer and therefore may not be reimbursed by the public system. The payer justifies its decision by stating that this would allow it to finance a different medicine, and from the public perspective this may be indeed legitimate. However, this would also mean that those individual patients that do need this medicine may still not be able to access it, unless they are able to afford it privately.

Moreover, from the perspective of the public, there is a clear need to ensure that focus on resolving risks associated with public spending on medicines that are available at present, does not jeopardise ongoing efforts to develop the medicines of the future. In other words, while it is justified to make the

¹⁹ PhRMA, *Profile Pharmaceutical Industry 2010*, http://www.phrma.org/sites/phrma.org/files/attachments/Profile_2010_FINAL.pdf

best informed decision about which medicines should be eligible for reimbursement today, there is also a need to ensure that in the future there would also be enough medicines to consider and choose from. This is especially important since we know that one medicine does not fit all and that patients benefit from the fact that a certain medical condition may be treated by a range of medicines. Therefore the question is quite simple: ***How do we share and shoulder the risk of bringing new medicines to the market and making the right decisions about financing these medicines?*** The answers are, of course, much more complex.

As will be seen in the case studies below, it is exceedingly difficult for payers and manufacturers to agree and set specific criteria whereby a medicine or treatment can be fairly judged as having worked or not. Indeed, in many cases the cost of designing these criteria and effectively monitoring the success and failure rate of a treatment and medication exceeds the financial benefit of the risk-sharing agreement.

Section 2: Survey of risk-sharing agreements

As section 1 has suggested, the term risk-sharing is used broadly to describe a range of schemes involving the sharing of cost and/or risk. Many risk-sharing schemes focus on sharing the cost burden of a new drug or medical treatment, which is technically not the same as the risk. How does this work in practice? The purpose of this section is to show how risk-sharing works in a sample of major OECD economies. This section illustrates that, in contrast to the tendency to consider risk-sharing as a simple and straightforward mechanism, designing and implementing effective risk-sharing schemes in practice is an arduous and very complex task.

In total, this study considered 27 risk-sharing agreements. Yet, as is made clear throughout the document, this is by no means every risk-sharing agreement, even within the five countries with which this study is concerned. When mentioned, pharmaceuticals are first referred to by their brand names with the pharmaceutical substance noted in parentheses, after which they are referred to by just their brand name.

2.1 Australia

Background

Australian healthcare is administered through Medicare Australia, a publicly-funded universal system that is mostly centralised. For pharmaceuticals, the Pharmaceutical Benefits Scheme (PBS) subsidises access to a wide-range of medicines by limiting the maximum payment for a patient at A\$33.30 (A\$5.40 for patients that receive concessions). The extra costs of medicines that exceed this amount are covered by the government, whilst all costs for medicines below the threshold are borne by the patient.

Drugs that are intended for reimbursement in this way must undergo a clinical and cost-effectiveness assessment by the PBAC, which decides whether reimbursement is possible. Once this has been made, the Pharmaceutical Benefits Pricing Authority (PBPA), acting on behalf of the government, negotiates with the pharmaceutical manufacturer as to the reimbursement price of the medicine on the PBS. Once an agreement is reached with both the PBAC and the PBPA, the product must receive formal approval from the minister for Health and Ageing, though it is unlikely that the minister would reject the drug at this point.

Australia, like many countries, has faced rising expenditure on medicines, due in part to the costs of new and often costly therapies, whilst expenditure on the PBS is rising by around 10% a year.²⁰ There is no public threshold for cost-effectiveness assessment by the PBAC, yet it is generally considered that any drugs costing more than A\$90,000 per quality-adjusted life year (QALY)²¹ are unlikely to be reimbursed, except for very rare conditions. Products for reimbursement that are expected to cost the public budget more than A\$10 million per year, and which have to be formally approved by the Australian Cabinet, are encouraged to be considered as part of a risk-sharing agreement with the product manufacturers.²² National data indicates that the PBPA is now more frequently suggesting risk-sharing agreements in negotiations with manufacturers and,

²⁰ Lu, C., et al, "Access to high cost drugs in Australia", *BMJ* volume 329, p416.

²¹ QALY is a measure of disease burden that includes both the quality and the quantity of life lived. For example, 4 years lived in a health status of 1 (full health), 5 years lived in a health status of 0.8 (fairly good health) and 20 years lived in a health status of 0.2 (very poor health) are worth the same to the surveyed patients – $4*1 = 5*0.8 = 20*0.2 = 4$ QALYs.

²² Barham, L., "Risk-sharing schemes – the Australian experience", *IMS Pharma Pricing & Reimbursement*, October 2008, Vol. 13, No. 10, pp.304-6.

whilst public information on existing schemes is limited, it is estimated that around 33 schemes are currently running.^{23,24}

A range of risk-sharing schemes are employed in Australia, including those that deal with drug utilisation, such as price volume agreements (PVAs) – for individual medicines as well as for a group of medicines treating a certain disease – and those that deal with drug performance, such as agreements that tie coverage to evidence development, or so-called 'outcomes research'. There are many different types of PVAs employed in Australia, including deals in which Medicare Australia recoups a percentage of the costs that exceed the annual budget for the medicine, or in which the manufacturer agrees to lower the price if a certain volume of sales is achieved. In addition, some schemes can involve manufacturers rebating a proportion of the cost for use outside of the restrictions set by the PBAC (non-subsidised use). In some schemes, a combination of models is used.

Particularly for performance-based agreements, several general conditions for participation have been established in order to rationalise utilisation of medicines.²⁵ For instance, patients must have a sufficiently severe case of the disease, they must have failed to adequately respond to cheaper existing therapies and must agree that they will only continue the new treatment if they achieve an adequate response, according to predetermined criteria. Quantifiable criteria must exist for enrolment in the scheme as well as for evaluating the level of response. A scheme is viewed most favourably when specific molecular markers exist that can predict the chances of a good treatment outcome in each patient, as well as measure *ex ante* the response. Frequent, often monthly, collection of data and re-evaluation is required. Furthermore, only specialist physicians may prescribe the medicine if it is to be reimbursed, in order to ensure that patients comply with the scheme.

Examples of risk-sharing agreements

Enbrel (etanercept)

Rheumatoid arthritis (RA) is an autoimmune disease affecting about half a million Australians that causes the patient's immune system to attack the healthy tissue in the lining of the joints, causing pain and swelling.²⁶ One possible treatment is Enbrel, manufactured outside North America by Wyeth Pharmaceuticals (now part of Pfizer Inc.). Enbrel belongs to a new class of medicines called biological disease modifying anti-rheumatic drugs (DMARDs), which block the natural substances that cause the inflammation thus lessening the symptoms and helping to stop further joint damage.²⁷

Enbrel was made available on the PBS in 2003 following an agreement between the drug's manufacturer, the PBAC and the Australian Rheumatology Association. Enbrel, along with its alternatives (Remicade (infliximab), Humira (adalimumab) and Kineret (anakinra)), had previously not been deemed cost-effective for reimbursement due to their relatively high cost per patient, per year, in addition to other uncertainties over longer-term safety.

²³ Medicines Australia, *Australian National Audit Office Performance Audit: Pharmaceutical Benefits Scheme*, p.16. See www.medicinesaustralia.com.au.

²⁴ Barham (2008), pp.304-6.

²⁵ *Ibid.*

²⁶ Arthritis Australia, Rheumatoid arthritis, See

http://www.arthritisaustralia.com.au/images/stories/documents/info_sheets/english/colour/template_RheumatoidArthritis.pdf

²⁷ *Ibid.*, Patient information on Ethanercept, See

http://www.arthritisaustralia.com.au/images/stories/documents/info_sheets/etanercept_280509.pdf

The agreement reached set conditions under which patients would be able to access the treatments, in order to ensure that products were targeted towards patients most likely to benefit from treatment. Prior to treatment, patients have to show a clinical need, i.e. a positive rheumatoid factor, and medicines can only be prescribed by a rheumatologist. In order to continue to receive treatment, patients must demonstrate a pre-determined clinical response every three months, based on rheumatoid factor, which they are required to consent to beforehand.²⁸

The government had calculated that the cost of the scheme would total around A\$140 million a year, yet Wyeth believed that it would not go over A\$100 million annually. In order to obtain an agreement Wyeth agreed to cover any spending required above A\$100 million, with this figure adjusted annually to take into account actual and expected consumption and expenditure.²⁹ Evidence since the agreement suggests that the expected amount of annual consumption has never been reached.³⁰

Tracleer (bosentan)

The drug Tracleer, manufactured by Actelion Pharmaceuticals, is a treatment for pulmonary hypertension (PH), which entails an abnormal increase in the blood pressure in the pulmonary arteries. Idiopathic pulmonary arterial hypertension (IPAH) is a rare, severe form of PH, occurring in 3-10 people per million of the population, which causes the patient to have a short life expectancy.

Owing to this, the PBAC had been unable to prove the cost-effectiveness of Tracleer for treatment of patients with IPAH over a fifteen year period. However, test models had indicated that if a set of continuation criteria were introduced at frequent intervals, it could be considered sufficiently cost effective. Therefore, a risk-sharing agreement was devised that would allow an ongoing patient registry of all patients treated by Tracleer to be maintained.³¹ Patients are re-evaluated during routine assessments every six months, recording the test results of echocardiograms and six minute walks, and using the data to determine eligibility for continuing treatment. Importantly, while the registry is managed by an independent academic centre, it is funded by the drug manufacturer. Therefore, the government bears the full cost of the treatment, but treatment failures are intended to be limited as much as possible through frequent re-evaluation and restricted continuation, funded by the manufacturer.

In 2008, the PBAC approved the listing of Tracleer on the PBS for pulmonary arterial hypertension, on the basis of acceptable cost effectiveness as compared with standard treatments. While it is not known whether the registry data supported this move, due to restrictions on the registry, it is likely that the registry provided a body of evidence to health authorities regarding patient response to Tracleer which aided their decision.

Analysis

The model of using cost effectiveness assessments for new health care technologies is well established in Australia.³² Therefore, it comes as no surprise that risk-sharing agreements have a major cost effectiveness

²⁸ Barham (2008), pp.304-6.

²⁹ *Ibid.*

³⁰ Carapinha, JL, "Setting the stage for risk-sharing agreements: international experiences and outcomes-based reimbursement", SA Farm Pract 2008, Vol. 50, No. 4, p.63.

³¹ See: Bosentan Patient Registry, 2005, <http://www.bosentanregistry.com.au/about/>.

³² Stockholm Network, *Theory versus Practice: Discussing the Governance of Health Technology Assessment Systems*, 2009. See http://www.stockholm-network.org/downloads/publications/Theory_versus_Practice.pdf

component, as compared with Italy, which, as will be seen below, has until recently relied mainly on monetary-based agreements. However, despite the use of evidence, cost sharing is based less on the performance of the medicine and more on its utilisation.

Some manufacturers have suggested that risk-sharing schemes could provide for faster approval times in Australia,³³ especially when bottlenecks in the pricing and reimbursement process exist, by for instance adding staff or streamlining the approach for assessing patients. In a recent review of HTA, published in December 2009 and implemented in part by Kevin Rudd's government in February 2010, it was made clear that there was a strong need for a more streamlined approach to drug approval that provided faster access for patients to the latest and effective treatments³⁴. The report also acknowledged the need to reduce the cost of the drug approval process for business and the not-for-profit sector³⁵.

Indeed, although the schemes are often viewed as overly burdensome, some stakeholders recognise that the requirements and process for administering the scheme ensures a more systematic, and in turn, effective, use of conventional and new treatments. In addition, many practitioners and patients have noted that the schemes help to improve compliance both of conventional treatments, with the incentive of getting to use a potentially much more effective therapy if help from the conventional therapy was exhausted, and new treatments, since patient compliance is often a condition of risk-sharing schemes.³⁶

However, it is also evident that some schemes can create bottlenecks themselves; the effect of schemes in speeding up patient access differs from scheme to scheme. Risk-sharing schemes involve several potential costs, including diagnostic tests, data collection and evaluation, as well as the cost to patients in the delay to access and the cost of getting schemes off the ground and operational. While risk-sharing schemes seem to be appropriate to control the cost of a small number of medicines, a 2009 report by the Australian National Audit Office stated that "it is not a mechanism that can be utilised across the board because of the overwhelming administrative burden on both Industry and Government".³⁷ In addition, this report found that certain schemes can cause "considerable delays in access for patients".

Health practitioners and patients confirm this added bureaucracy and administrative burden, with rheumatologists, nurses and RA patients having complained of "excessive bureaucracy".³⁸ Specifically, they have cited the application process, the amount of laboratory tests and joint assessments as seriously affecting short-staffed rheumatologists' offices and hospitals. In particular, patients noted that it was quite difficult to familiarise themselves with the scheme, lacking sufficient information about the scheme as well as the rationale for restricting access and for the eligibility criteria. Both groups also stated that access criteria are not reassessed and refined as the scheme progresses, so that there is no assessment as to the appropriateness of the criteria over the long-term.

³³ Barham (2008), pp.304-6.

³⁴ Australian Government Department of Health and Ageing, *Review of Health Technology Assessment in Australia*, See [http://www.health.gov.au/internet/main/publishing.nsf/Content/00E847C9D69395B9CA25768F007F589A/\\$File/hta-review-report.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/00E847C9D69395B9CA25768F007F589A/$File/hta-review-report.pdf).

³⁵ Department of Health and Ageing, Streamlined Approvals Process for Medical Advances, See <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/mr-yr10-nr-nr036.htm>.

³⁶ Lu, C., et al, "The views of stakeholders on controlled access schemes for high-cost anti-rheumatic biological medicines in Australia", *Australia and New Zealand Health Policy*, 2007, Vol. 4, No. 26.

³⁷ Medicines Australia, p.12.

³⁸ Lu, C., et al, (2007).

It is also important to note that in some risk-sharing schemes, such as the agreement to reimburse Enbrel, concerns continued to be raised about the ability to access the treatments made available. In particular, the requirement that prescriptions had to be made by a rheumatologist blocked many patients as the number of these specialists is limited, varying between states and territories. Ultimately, the use of Enbrel was shown to roughly correlate with the per capita ratio of rheumatologists, while prescription data by rural, remote and metropolitan areas shows a geographical heterogeneity in access to health care.³⁹

Overall, the Australian National Audit Office report recommended that for risk-sharing schemes to be cost effective for a limited use there needs to be a better definition of the medications and indications for which risk-sharing schemes are appropriate, as well as a more accurate model for determining utilisation. Furthermore, there needs to be more certainty around timelines for patients. Nevertheless, such efforts will need to take into account that, the more schemes that are created and the larger the amount of initial participants, the harder it will be to accurately predict patient consumption of these medicines.

2.2 Germany

Background

Health care in Germany is mainly funded through a statutory contribution system which provides free health care for all through what are known as “sickness funds”, or statutory health insurance (SHI) schemes. Around 240 SHI funds cover approximately 90% of the German population. The Federal Joint Committee (G-BA) is the main policymaking body in German health care; its responsibilities involve determining the benefit package of SHI and, up until recently, making reimbursement decisions.

In the last few years, changes to German law have fundamentally altered pricing and reimbursement negotiations with the pharmaceutical industry. Based on the *Federal Law to Increase Competition among Statutory Health Insurance Funds* introduced in 2007, SHI funds must provide one fixed premium; therefore, competition between funds relies primarily on the quality of health care services provided.⁴⁰ In addition, German law now allows SHI funds, instead of the G-BA, to negotiate contracts directly with pharmaceutical manufacturers. Hence, there is now a drive among SHI funds to make the most of these negotiations to create market advantages based on both price and quality, including via alternative models such as risk and cost-sharing schemes. Also as a result, risk-sharing agreements in Germany take place at the regional or individual sick fund level, not at the national level.

Pharmaceutical companies also have an incentive to participate in risk-sharing agreements for German markets. Germany constitutes one of Europe's largest pharmaceutical markets with a population of over 80 million and German pricing levels are often taken as a reference in other European countries. Furthermore, the prices used in Germany are set by manufacturers. Therefore, manufacturers often prefer agreements on top of direct discounts, based on the idea that there is a reduced chance of price cuts spreading to other markets.

³⁹ Lu, C., et al, *The funding and use of high-cost medicines in Australia: the example of anti-rheumatic biological medicines*. See <http://www.anzhealthpolicy.com/content/4/1/2>

⁴⁰ Hogan and Hartson, “Risk-sharing and other new business models for pharmaceutical companies in Germany”, *Pharmaceutical and Biotechnology Update*, August 2008.

Initially, negotiations between sick funds and manufacturers focused on discount agreements for generic drugs. However, the trend in the last few years is to arrange deals involving patented medicines as well, including new and costly medicines. Risk-sharing agreements tend to involve pay for performance deals and schemes which focus on paying for utilisation over an agreed amount, effectively PVAs.⁴¹

Examples of risk-sharing agreements

Aclasta (zoledronate)

Aclasta is a treatment for postmenopausal women and men with osteoporosis, a bone disease that leads to an increased risk of fracture. In 2007, the manufacturer Novartis negotiated a risk-sharing agreement with two SHI funds, namely the Germany Employee Fund (DAK) and Barmer Fund (BEK) – which together account for 30% of the health insured population. As part of the agreement, Novartis agreed to reimburse the full costs of the medicine for patients for whom the treatment had failed. Treatment failure was clearly defined and required, for example, the experience of a fracture or an organ rejection within the first year of treatment.

It is interesting to note that this risk assessment does not incorporate other determinants of treatment success or failure, such as the disease course, age of the patient, potential interactions with other medicines, etc. This factor may perhaps increase the risk for both the payer and manufacturer unnecessarily.⁴²

The success of this agreement is still unclear. Whilst Novartis has indicated a greater uptake in Aclasta through the scheme, some, such as German consultants Booz & Co, have suggested that sales of Aclasta have not increased significantly.⁴³ What is clear is that on the back of this agreement Novartis has made similar arrangements with both DAK and BEK for three other products, Sandimmune (cyclosporine), Myfortic (mycophenolate sodium) and Certican (everolimus)⁴⁴, indicating that both parties have been pleased with the Aclasta deal and are looking to seek further arrangements in future.

Avastin (bevacizumab) + Taxol (paclitaxel)

An agreement in 2007 between Roche and several SHI funds allowed Avastin, an anti-cancer agent, to be co-administered with Taxol (paclitaxel), a chemotherapy drug, to test if the combination could extend patient survival in both metastatic breast cancer and metastatic renal cell carcinoma. Under the terms of the deal, Roche agreed to provide full or partial reimbursement for cases in which the treatment exceeded a specific total dosage over a certain period of time. In the meantime, the Avastin + Taxol combination would have the opportunity to be tested in real world environment.

Ultimately, an extension of survival by the combination therapy could not be shown, as compared to Taxol on its own. In part, this may have been because at least 23% of patients had to discontinue treatment early due to toxicity issues or other complications. Consequently, most patients did not reach the total dose agreed in the contract.

⁴¹ *Ibid.*

⁴² Drug Commission of the German Medical Association, "Opinion on 'cost sharing initiatives' and 'risk-sharing contracts' between pharmaceutical manufacturers, health insurers and hospitals" ("Stellungnahme zu „Cost-Sharing-Initiativen“ und „Risk-Share-Verträgen“ zwischen pharmazeutischen Herstellern und Krankenkassen bzw. Kliniken"), May 2008.

⁴³ Senior (2009), pp.4.

⁴⁴ *Ibid.*, pp.4-5.

Enbrel (etanercept)

Again, Wyeth pharmaceuticals engaged in a risk-sharing agreement for the rheumatoid arthritis drug Enbrel, this time with Taunus BKK, the third largest SHI fund in Germany. In this agreement, reached in 2008, Wyeth agreed to fund and provide compliance support to patients taking Enbrel, significantly improving the effectiveness of the treatment. As an injectable biologic, Enbrel's effectiveness is highly dependent on the compliance of its patients, in particular when considering that a third of prescriptions are discontinued because of ineffectiveness within the first three months due, partly, to a lack of compliance. The support offered by Wyeth included homecare visits by qualified nurses, a telephone-line support service and the promotion of regular patient communications about treatment, including tips about how to self-inject and the importance of maintaining therapy.

By improving the compliance of patients taking Enbrel, patients have been able to experience a more effective treatment, which they have been able to remain on for relatively longer. Since the scheme, Enbrel has shown a more positive sales trend than its competitors and Wyeth has expanded the deal to over 100 other German sick funds, with some even eliminating co-payments on the drug to improve uptake.⁴⁵

Analysis

The examples discussed here cannot be described as true risk-sharing agreements, and in many cases do not involve shared cost either. Risk and cost are largely borne by either the SHI fund or the manufacturer, but not both.

But other stakeholders have not been pleased with the result either. Although risk-sharing schemes allow sponsor companies to gain a kind of 'preferred status' among competitors, industry experts have said that reaching and sustaining preferred sales volumes has been hard under risk-sharing schemes. In addition, identifying the appropriate eligibility and response criteria, as well as ensuring compliance, has proved to be challenging, especially with regards to accurately assessing the risk of therapy failures.⁴⁶ As a result, risk-sharing agreements seem to have been most effective for treatment for which success (or failure) is simple to assess.

Moreover, health care practitioners have not seen much benefit in risk-sharing schemes. Although a 2008 report by the Drug Commission of the German Medical Association mentions that drug schemes may speed up access to treatment, physicians tend to dislike them because of the limitation on their ability to select treatment, dosages and patient response indicators.⁴⁷ In addition, the report suggests that only marginal cost savings are achieved through the schemes in place in Germany. Physicians also question the ethics of many of the schemes, saying they are not transparent – according to a survey by the Medical Association of the North Rhine, 63% of doctors complain about the lack of transparency, saying that there is not enough information given to patients and providers on the structure and benefits of the schemes.⁴⁸ They may also pose risks to patient safety, since the safety risks are often not well-characterised beforehand. In addition, they say that clearly-defined, evidence-based parameters for measuring success of the therapy are often missing. Furthermore, the costs, in terms of red tape (i.e. collection of data, documentation and billing) that doctors, hospitals and even payers face in the schemes outweigh the savings that are gained.

⁴⁵ *Ibid.*, pp.2-3.

⁴⁶ Hogan and Hartson, 2008.

⁴⁷ Drug Commission of the German Medical Association, 2008.

⁴⁸ Leschet, VM., "Risk- und Cost-Sharing - ein Modell, das bei Ärzten auf Vorbehalte stößt" ("Risk and Cost-sharing - a model that meets with doctors on reservations"), *Ärzte Zeitung (Medical Journal)*, October 2008.

Based on these concerns, experts are questioning the sustainability of schemes involving evidence collection and drug performance indicators, especially when it comes to drugs treating relatively larger patient groups. Indeed, Sasha Richardson, principal consultant at Bridgehead International, a pharmaceutical and health care consultancy, predicts that financial rather than performance-based schemes will become more common in Germany, since they involve fewer logistical complexities and are less difficult to scale up, and hence are more sustainable.⁴⁹

2.3 Italy

Background

In Italy, health care is mainly provided through a regionally based National Health System (SSN), which provides universal coverage free of charge at the point of use. Pharmaceutical coverage is based on the National Pharmaceutical Formulary (PFN), a list of the medicines which the SSN has agreed to reimburse. The PFN is managed by the Italian Medicines Agency (AIFA), which operates under the direction of the Ministry of Health. As part of its duties, AIFA is responsible for the pricing of drugs on the PFN through negotiation with pharmaceutical companies and for monitoring pharmaceutical expenditure at the national and regional level. Regional and local health care authorities may also make reimbursement decisions on top of AIFA, but certain agreements, including risk-sharing deals, are managed and delivered entirely from the central level.

Health care institutions in Italy, especially hospitals, are increasingly facing budget shortfalls – €1.7 billion in 2009 and €2.3 billion expected in 2010.⁵⁰ Health authorities are working to rationalise health care, including eliminating any inappropriate use of medicines. Hence, there is a push to monitor and regulate the use of costly medicines, whilst still allowing patients to access new treatments. In this context, the use of risk-sharing schemes in the negotiation process for expensive and potentially innovative medicines, which are expected to represent a clinical improvement on existing therapies, is becoming more and more common – among oncology medicines it is now almost obligatory. The first risk-sharing agreements, involving cancer drugs, were initiated in 2006. As of the end of 2009, schemes for at least 25 therapies existed, with around 40,000 patients enrolled in total.⁵¹

Risk-sharing schemes in Italy are mainly focused on identifying the value of new medicines and the patient groups in which they are most effective, as well as sharing the cost of this process with manufacturers. For cancer drugs in particular, the view is that in many cases the efficacy of new therapies is unpredictable and a satisfactory clinical response is achieved only in a limited number of cases, in the context of very high costs.⁵² Therefore, the SSN seeks agreements with manufacturers in which it only bears part of the cost of evaluating the medicine in clinical practice. The intended result is that ultimately, only the most effective medicines are provided on the PFN, at a cost saving to the SSN.

⁴⁹ Senior (2009), p.6.

⁵⁰ "Faster market access in Italy for oncology drugs with risk-sharing deals – study", *APM Health Europe*, 27 April 2010, <http://www.apmhealthurope.com/nostory.php?numero=18805&ctx=7ad9a92f6fcd467517570ac5a4c80b19>.

⁵¹ Swedish Medical Products Agency, *Assessing Drug Effectiveness – Common Opportunities and Challenges for Europe*, Swedish EU Presidency, Post-Conference Booklet, 29 July 2009, pp.11-2.

⁵² AIFA, *National Report*, 2007, p.7.

Risk-sharing deals are either monetary or performance-based and generally take one of three forms⁵³: 1) a discount, usually 50%, on the cost of the first cycle(s) of treatment; 2) a 50% price reduction for non-responding patients, in which the SSN reimburses the full price of the initial treatment, but in the case of non-responders the manufacturer pays back 50% of the treatment cost to the SSN; and 3) payment by performance, in which the SSN also reimburses the first cycle of treatment at full price, after which it receives a full payback from the manufacturer for non-responders. For the second two schemes, patients are monitored by regional specialist centres and evaluated according to pre-determined criteria for disease progression.⁵⁴ A nationwide registry for collecting data and monitoring patients throughout the process of treatment is now well established. Some schemes also involve price ceilings, as additional cost sharing components, for instance on the total annual cost of treatment per patient. For example, the cost of the colon cancer treatment, Avastin, cannot exceed €25,941 per year.⁵⁵

Examples of risk-sharing agreements

Oncology drugs

There are several existing schemes that involve risk-sharing arrangements for cancer drugs and the structure of the deals varies. In 2006, three deals were established that allowed access to: Tarceva (erlotinib), for patients with lung cancer; Sutent (sunitinib), for the treatment of advanced or metastatic renal cancer; and Nexavar (sorafenib), also for treating renal cancer. These deals agreed to impose a 50% discount for the SSN when used in the first two or three cycles of treatment. Similarly, Sprycel (dasatinib), which treats two types of leukaemia, was discounted in 2007 by 50% for the first cycle of treatments after an established progression, based on cytogenetic response. This scheme utilised price reductions for non-responders, but did not offer full compensation from the manufacturer – in these schemes, the SSN ultimately pays at least half of the cost of the therapy no matter the outcome.⁵⁶

More recently in 2008, schemes were agreed that saw Avastin, Tassigna (nilotinib) for chronic myeloid leukaemia and Nexavar – this time for liver cancer – available for reimbursement. For Tassigna and Nexavar, the agreements saw the SSN pay the full price for the first cycles, either before or after the cycle is administered, and then it is compensated *ex post* for the full price for treatment failures.

Aclasta (zoledronate)

As we have seen from the German deal in 2007, Novartis were willing to negotiate risk-sharing agreements for Aclasta, a treatment for osteoporosis that reduces the incidence of new clinical fractures. In 2009, an agreement was reached with AIFA whereby Novartis would cover the costs of not just their product, but also the associated hospitalisation and nursing care cost, of any fracture resulting from treatment failure. This took the agreement beyond previous agreements and saw the manufacturer take on the risks of associated costs related to treatment failure. Novartis has been keen to make clear that this scheme is a pilot study, and it does not envisage its use on a broad scale.⁵⁷

⁵³ Toumi, M., "Risk-sharing: when eagerness leads to loss", Creativ-Ceutical, 2009.

⁵⁴ Rasi, G., "Perspectives on European collaboration in connection with the follow-up of drug effectiveness", presentation given at EU conference: Assessing Drug Effectiveness – Common Opportunities and Challenges for Europe, Stockholm, 29 July 2009.

⁵⁵ Jirillo, A., Vascon, F. & Giacobbo, M., "Bevacizumab in advanced cancer, too much or too little?", *Annals of Oncology*, Vol. 19, Iss. 10.

⁵⁶ "Risk-sharing e rimborso in base al risultato" (Risk-sharing and reimbursement based on results), *Politica Sanitaria*, No.5, 2008.

⁵⁷ Senior, M., "Pricing Experiments: Pharmas Get Creative in Germany", *In Vivo*, July/August 2009, Vol. 27, No. 7, p.4.

Analysis

In Italy, risk-sharing agreements mainly try to reduce the cost to the SSN for new medicines, as a way of rationalising health care expenditure and allowing patients to access treatments and medicines. The goal is to limit pharmaceutical spending to the most effective medicines, and increasingly, to the patients in whom they will be most effective. It is interesting to note that it is the cost of the treatment and not the cost of measuring and evaluating the treatment that the SSN seeks to share with manufacturers, even though the evidence collection process can actually be quite expensive.

This means that with two major exceptions, the schemes in Italy are not true risk-sharing agreements – ultimately, the SSN does not bear any risk that treatments will fail because the manufacturer pays for the full cost of these treatments. The SSN pays for successful treatments and the manufacturer pays for failed treatments. Hence, they are cost-sharing, rather than risk-sharing schemes.

However, in the case of discount schemes and price reduction schemes, SSN pays for at least half of the cost of treatment, no matter whether it succeeds or fails – there is no full *ex post* compensation by the manufacturer for treatment failures. These schemes can be considered to actually share the risk of ineffective treatments between the manufacturer and the SSN, because the SSN pays a part of the cost, equal to half of the market price of the drug. It should be noted, though, that the trend is now moving away from these models towards pay for performance schemes.

Regardless of the model, these schemes seem to be making new medicines available to patients that would otherwise be considered as too expensive for the SSN to include on the PFN. AIFA has found that risk-sharing schemes in Italy seem to have facilitated quicker access to some newly approved medicines.⁵⁸ A joint study carried out by AIFA and Rome's Tor Vergata University (2010) suggests that patients in Italy have access to innovative oncology therapies earlier if they are approved with (centralised) risk-sharing or conditional reimbursement agreements, as compared to conventional listing in the national and regional (or hospital) formularies.⁵⁹ This seems to suggest that the necessary framework for the schemes is now well established, allowing agreements to be reached and eligible patients to be determined relatively quickly.

Health care practitioners seem to be more satisfied with the results that risk-sharing schemes have produced. A survey by Italian pollster SWG has found that one in two cancer specialists believes that risk-sharing and pay for performance agreements are the “way forward”.⁶⁰ Besides improving patient access to new medicines, it has actually improved the utilisation of the medicines by prescribers, thus improving the medicines' effectiveness. However, practitioners also note that risk-sharing schemes are not a panacea and are still quite expensive. 40% of respondents believe that therapies and the appropriate targeting of therapies can be improved further. This suggests that they view some agreements as expensive experiments and that perhaps risk-sharing schemes should be limited to those with the greatest clinical rationale.

Given the number of schemes agreed over the last four years, manufacturers appear to comply with what is now the *status quo* for reimbursement negotiations for new medicines that are considered to be more costly.

⁵⁸ Rasi, G., “Perspectives on European collaboration in connection with the follow-up of drug effectiveness”, presentation given at EU conference: Assessing Drug Effectiveness – Common Opportunities and Challenges for Europe, Stockholm, 29 July 2009.

⁵⁹ Russo, P., Mennini, F., Siviero, P. & Rasi, G., “Time to market and patient access to new oncology products in Italy: a multistep pathway from European context to regional health care providers”, *Annals of Oncology*, March 2010.

⁶⁰ “Italy to reimburse Novartis' Lucentis in cost control agreement”, *APM Health Europe*, 24 March 2009, <http://www.apmhealthurope.com/story.php?numero=L14660>.

Probably the fact that in some cases manufacturers do not bear the full risk of treatment failures, or the cost of monitoring patients, helps incentivise their participation. In addition, communication and cooperation between AIFA and several manufacturers is well established and probably helps to drive the process. Furthermore, manufacturers have said they benefit from the evidence collection process (that is mainly borne by the SSN) and from being able to ensure that the drug is appropriately prescribed.⁶¹ Nevertheless, especially for oncology drugs, manufacturers seem to have little choice but to agree to a risk-sharing deal if they want their product to gain access to the Italian market.

Despite the cost of monitoring patients in the schemes, the AIFA and SSN seem to find value in existing risk-sharing schemes, with regards to health care savings and the quality of treatments available to patients. Guido Rasi, the director of AIFA, has publicly promoted the existing schemes, saying that they help bring savings to the health budget and are sustainable.⁶² (This may be in part due to the fact that the schemes are all administered centrally, as opposed to through the complex regional system.) Furthermore, the number of schemes continues to grow.

However, risk-sharing schemes in Italy are still relatively young, especially the schemes involving evidence collection. At this point, they seem to accomplish the intended objectives of improving patient access to new drugs whilst limiting spending. Also, most schemes are geared toward a small number of specialised medicines and relatively small patient groups. However, it remains to be seen how costly they will prove to be over the next few years – for both the SSN and manufacturers – as schemes move more towards evidence collection and full repayment models.

2.4 United Kingdom

Background

The NHS provides universal health care coverage, funded by general taxation, with all health services free at the point of entry. One rare exception to this applies to prescribed pharmaceuticals, for which the NHS requires some patients in England to pay a fixed co-payment or prescription charge (currently £7.20). However, this affects only around 10% of all pharmaceuticals prescribed in the NHS⁶³. Pharmaceuticals that are available through the NHS are approved by the Department of Health (DH), which for more expensive drugs often relies on a cost-effectiveness analysis conducted by NICE. Usually, drugs that are calculated as costing between £20,000 and £30,000 per QALY are considered in this way, while drugs over £30,000 are often rejected.

In general, the NHS operates a free pricing system for pharmaceuticals, allowing manufacturers to set prices without any maximum ceilings. Pharmaceutical prices are instead influenced through profit controls, specifically the Pharmaceutical Price Regulation Scheme (PPRS), a voluntary agreement between the DH and the Association of the British Pharmaceutical Industry (ABPI) covering all branded prescription medicines sold in the NHS. The PPRS restricts the profits for pharmaceutical companies, after taking into account research, marketing and administration costs. Around 80% of pharmaceuticals reimbursed through the NHS are regulated in this way, the rest are likely to be generic medicines that are controlled by the NHS Business Services Authority (NHSBSA). In total, the NHS spends around £9 billion on branded pharmaceuticals and

⁶¹ *APM Health Europe*, 2009.

⁶² Rasi, G., 2009.

⁶³ NHS – Prescriptions. See <http://www.nhs.uk/nhsengland/Healthcosts/pages/Prescriptioncosts.aspx>

the PPRS is a mechanism by which the DH attempts to bring this figure down.⁶⁴ Each PPRS agreement, often spanning five years, will impose requirements on the pharmaceutical industry to reduce prices. For example, the current arrangement enforces two separate price cuts spaced one year apart (3.9% and 1.9%).⁶⁵

The concept of risk-sharing has gained much traction in the UK recently, in response to growing public discontent around unavailable drugs in the NHS. A recent Office for Fair Trading report identified that risk-sharing schemes in the NHS are offering an opportunity to “help coordinate the expectations of the payer and manufacturers” and argued that “they may allow for more predictable uptake for manufacturers, and predictable health gains for a given expenditure for the NHS for drugs for which an agreement may not be able to be reached otherwise”.⁶⁶ However, the same report expressed concerns about the overly burdensome nature of the contracts to agree and audit, given the information and resource constraints. In general, it concluded that such arrangements in the current pricing system should only be used in a “limited number of cases – where there is genuine doubt about the efficacy of a drug and reasonable expectations that uncertainty can be addressed within a reasonable timescale”, i.e. they should remain the exception not the norm. Recent comments by the Sir Michael Rawlins, the chairman of NICE, also suggests that some policymakers see risk-sharing schemes as overly complicated, in many cases calling for a simple discount on pharmaceuticals.⁶⁷

The most recent PPRS agreement promoted the use of “patient access schemes”, the preferred terminology for risk-sharing in England and Wales. It says that such schemes “facilitate earlier patient access to medicines that are not in the first instance found to be cost and clinically effective by NICE” and set out some key principles about how schemes should be performed, as well as committing to reviewing patient access schemes within two years of the new agreement.⁶⁸ Yet what is most likely to have the biggest impact on the future of risk-sharing in the NHS is the move to a value-based pricing system for pharmaceuticals, which the current UK coalition government plans to introduce from 2013/14 to replace the PPRS.⁶⁹ This new system of drug pricing will set prices according to the value medicines provide, meaning that NICE will no longer set cost-effectiveness thresholds. It would also be designed to support the “use of risk-sharing schemes to enable early uptake of new medicines which lack cost-effectiveness data”.⁷⁰

The main examples of risk-sharing schemes that have had an impact in the UK, which will be outlined now, are those agreed for treating multiple sclerosis, multiple myeloma and “wet” age-related macular degeneration. It also important to note that there have also been recognized examples where NICE has rejected risk-sharing proposals from pharmaceutical companies, in favour of making the drug unavailable for reimbursement.⁷¹

⁶⁴ Department of Health, Pharmaceutical Price Regulation Scheme. See <http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalpriceregulationscheme/index.htm>.

⁶⁵ Department of Health, 2009 PPRS. See <http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalpriceregulationscheme/2009PPRS/index.htm>.

⁶⁶ Office of Fair Trading, *The Pharmaceutical Price Regulation Scheme*, p92. See http://www.of.gov.uk/shared_of/reports/comp_policy/oft885.pdf.

⁶⁷ “NHS drugs adviser questions price policy”, *Financial Times*, 23 August 2010. See <http://www.ft.com/cms/s/0/9a135568-aed7-11df-8e45-00144feabdc0.html>.

⁶⁸ Bridgehead International, *New PPRS Scheme*. See http://www.ispor.org/signs/HTA_EBR/UK_PPRS031209.pdf.

⁶⁹ Department of Health, *Equity and excellence: Liberating the NHS*, p26. See http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_117794.pdf.

⁷⁰ Conservative Party, *Improving access to new drugs: a plan to renew The National Institute for Health and Clinical Excellence (NICE)*. See <http://www.conservatives.com/~media/Files/Policy%20Documents/NICE%20Policy%20Document.ashx?dl=true>.

⁷¹ “Avastin prolongs life but drug is too expensive for NHS patients, says Nice”, *The Guardian*, 24 August 2010. See <http://www.guardian.co.uk/society/2010/aug/24/avastin-too-expensive-for-patients>.

Examples

Avonex (beta-interferon 1a), Rebif (beta-interferon 1a), Betaferon (beta-interferon 1b) and Copaxone (glatiramer acetate)

After a lengthy process, NICE rejected four drugs, manufactured by four different companies (Biogen Idec, Merck Serono, Schering AG (now Bayer Schering Pharma) and TEVA/Aventis) in January 2002 for the treatment of multiple sclerosis (MS), a disabling neurological disease. In particular, NICE identified in its report a large variation between estimates as to the cost per QALY for any of the drugs – with one estimate of £10,000 per QALY (offered by commercial-in confidence data supplied by one of the manufacturers) and another of \$3 million per QALY (by an American research group).⁷²

In response to the NICE guidance, the manufacturers of the drugs reached an agreement with DH to undertake a long-term trial, whereby the drug would be available through the NHS. Drugs would be offered to relapsing, remitting MS sufferers or patients with a secondary progressive form of MS with relapses and if they matched criteria drawn up by the Association of British Neurologists (ABN) in 2001. As well as extending coverage, the deal also allowed evidence on the effectiveness of the drug to be developed. Under the terms of the arrangement, a cost-effectiveness threshold of £36,000 per QALY would be maintained throughout, with price adjustments occurring to ensure the ceiling is upheld. Therefore, if the drugs are found to cost more than £36,000 per QALY their price will need to be reduced, whilst drugs found to be below the £36,000 ceiling are able to increase in price. The agreement set a minimum of 5,000 participating patients and envisaged that around 7,500-9,000 patients would eventually be included in the ten year study, which is set to end in 2012⁷³.

Interim results of the scheme were published in 2010. They showed how patients had measured on the Expanded Disability Status Scale (EDSS), a tool used to monitor neurological impairment in MS as a marker of disease progression. Patients are monitored annually and the results are compared to expected outcomes to establish a deviation score. Patients can then be assessed as being better off than expected (a negative deviation), worse off than expected (a positive deviation) or the same as expected (a zero score). EDSS is also used as a basis for determining price adjustments. In the first two-year results, 4,749 patients were monitored and a positive deviation score was noted of 113%. However, some researchers question the accuracy of these results, suggesting that there are uncertainties that render them unreliable. As a result, more emphasis is now being placed on further evidence that may present itself as the scheme progresses towards a conclusion⁷⁴.

These interim results are not the only evidence to question the effectiveness of the MS risk-sharing scheme. A 2007 UK House of Commons Health Select Committee report studied the scheme, publishing the testimony of Professor Jon Nicholl, who led the study at Sheffield University for the first three years. Professor Nicholl told the Health Select Committee that the evidence obtained from the MS scheme was “weak” and that

⁷² National Institute for Health and Clinical Excellence, *Beta interferon and glatiramer acetate for the treatment of multiple sclerosis*, p6. See <http://www.nice.org.uk/nicemedia/live/11441/32290/32290.pdf>.

⁷³ Pharmaceutical Forum, *Risk-Sharing practices and Conditional Pricing of Pharmaceuticals*, p4. See http://ec.europa.eu/pharmaforum/docs/pricing_risk_en.pdf.

⁷⁴ IMS Health, “UK: Interim Results of Multiple Sclerosis Risk-Sharing Scheme”, *PHARMA: Pricing and Reimbursement*, March 2010, Vol 15, No.3, p63.

Sheffield University had decided not to bid for the remaining seven years of the contract because “we were less certain about the ability of the scheme to deliver the science that we hoped it would.”⁷⁵

Velcade (bortezomib)

In 2007, DH launched a cost-sharing arrangement with the pharmaceutical company Johnson & Johnson, which allowed the drug Velcade to be made available to sufferers of relapsed multiple myeloma, a cancer of the plasma cells located in the bone marrow, who were unable to have bone transplantation. A NICE appraisal of Velcade had previously calculated that it would cost the NHS £33,500 per QALY to provide the drug to NHS patients, slightly above NICE’s £30,000 threshold. In the negotiations, Johnson & Johnson maintained that if other additional relevant factors were considered in NICE’s evaluation, such as the innovative nature of Velcade and the features of the condition and population receiving the technology, the product would be able to prove its cost-effectiveness and justify a positive assessment by NICE.

In order to allow the drug company to prove this, NICE agreed to a risk-sharing scheme that sees the NHS initially cover the costs of treatment for a specific set of patients, i.e. patients that suffer from progressive multiple myeloma, with a first relapse, after one prior therapy attempt and with a bone transplant no longer an option.⁷⁶ If, after four treatment cycles, a serum protein test shows a reduction of 25% or more then the treatment is deemed to have been effective. However, if it shows a non-response of less than 25% reduction, then the pharmaceutical company rebates the NHS the total costs of the four cycles. Based on expected response rates, NICE expects the NHS to reimburse 85% of the total costs of Velcade provided through this scheme, which would make the cost of the drug under the scheme £30,800 per QALY, still fractionally above NICE’s tolerable limit.⁷⁷ NICE argues, however, that the scheme can allow the cost effectiveness of Velcade to be improved, which could lead to a future positive approval. The scheme will continue to run until reviewed by NICE at a further date.

Lucentis (ranibizumab)

Age-related macular degeneration (AMD) is a condition that gradually destroys the central vision of patients in the later stages of their life, and is the leading cause of blindness in the UK. In its rarer “wet” form, which relates to around 10% of AMD sufferers, the loss of central vision can occur much quicker than the slower “dry” form, for which there is no treatment. There are three known treatments for “wet” AMD. The first is Lucentis, a drug manufactured by Novartis that is injected into the eye. The other two possible treatments are Macugen (pegaptanib), manufactured by Pfizer, and the more recent treatment Avastin (Bevacizumab), which is traditionally manufactured for treating bowel cancer by Genentech/Roche. Draft NICE guidance in 2007 approved the use of Lucentis for treating a fifth of patients with “wet” AMD, specifying that it should only be used once patients had already lost their sight in one eye. The response to this was much anger from the public and patient groups, with NICE receiving over 20,000 responses from individuals and organisations expressing concern in July 2007.⁷⁸

After a consultation period, an agreement was then reached between the manufacturers and DH that allowed many more patients to receive Lucentis, incorporating patients with significant sight loss (up to visual acuity 9/96). The agreement was a risk-sharing scheme that saw patients in England and Wales receive 14

⁷⁵ House of Commons Health Committee, *National Institute for Health and Clinical Excellence, First Report of Session 2007–08*, p90. See <http://www.publications.parliament.uk/pa/cm200708/cmselect/cmhealth/27/27.pdf>.

⁷⁶ Pharmaceutical Forum, p3

⁷⁷ NICE, *Summary of VELCADE® Response Scheme*.

⁷⁸ Royal National Institute of Blind People, Access to AMD Treatment. See <http://www.mib.org.uk/getinvolved/campaign/yoursight/amdcampaign/accesstreatment/Pages/default.aspx>.

injections of Lucentis, which the manufacturer claims should be enough for most patients to benefit from the treatment, reimbursed by the NHS, whilst any further injections would be covered by Novartis. In addition, NICE prohibited the use of Macugen, whilst it is yet to sanction the use of Avastin for treating “wet” AMD, despite it being significantly cheaper.⁷⁹

Analysis

The NHS probably provides a suitable environment for risk-sharing schemes to appear attractive. Its centralised nature, wholly funded by taxpayers, means that a patient can lose the opportunity of accessing an expensive innovative pharmaceutical on the grounds that the costs of providing such drugs to everyone are considered to be too high according to the threshold (i.e. cost per QALY) put forward by the NHS. Whilst the NHS is by no means alone in assessing the cost-effectiveness of drugs, the breadth of its coverage in England and Wales means that drugs rejected for use in the NHS are effectively excluded from the entire health care system, barring a small collection of private health insurers. As a consequence, risk-sharing in the NHS has only ever really been resorted to in response to the rejection of drugs for reimbursement by NICE and is not yet a part of the original drug approval process, despite calls from NICE’s chief executive Sir Andrew Dillon for it to be included. Instead, it is mainly an afterthought prepared at the last minute to save the drug approval process from collapse.

Reimbursement decisions that deny access to high-end medicines are also highly politicised, due in part to the fact that money spent on pharmaceuticals comes directly from public funds. As a result, rightly or wrongly, decisions about whether a specific drug should be reimbursed are potentially weighed up against all other items of public spending. While NICE is able to make these decisions directly, very often politicians will be called to account for them, particularly the Secretary of State for Health or a patient’s Member of Parliament. As a result, it is perhaps unsurprising that policymakers are keen to explore the potential for risk-sharing, particularly if it allows for greater patient access to expensive innovative treatments.

The current coalition government certainly sees risk-sharing in this way, allowing the UK government to increase patient access, whilst not burdening the NHS with the obligation of reimbursing treatments that are considered to be less effective than anticipated at a time of financial uncertainty. A lot is still unknown about the exact plans of the new UK government, although what is clear is that they see risk-sharing as an integral part of the move towards a value-based pricing system for pharmaceuticals over the next three to four years. In an article written when he was the Shadow Secretary for Health, Andrew Lansley, now Health Secretary, discussed how he actually helped to facilitate the deal reached by Johnson & Johnson and the DH to allowing one of his constituents to receive Velcade, asking:

Why on earth can’t this be applied generally? Instead of the NHS denying access to drugs because they say it’s not cost-effective we should encourage the NHS to use new medicines which are clinically effective, and agree subsequently to pay the drugs companies according to the therapeutic benefit. In other words, drugs companies should only be paid according to the benefits that a drug brings to patients. NICE should be involved in this process, working with drug companies to set fair prices for new medicines – rather than refusing new treatments which it deems too expensive. Our proposals will mean better access to new drugs for more patients at exactly the same cost as the current system. It is an innovative solution to a critical problem.⁸⁰

⁷⁹ *Reuters*, “NICE backs Lucentis for blindness treatment”. See <http://uk.reuters.com/article/idUKL1388321720070614>.

⁸⁰ “Nice doesn’t have to be nasty”, *The Daily Telegraph*. See <http://www.telegraph.co.uk/news/newstoppers/politics/conservative/2778257/Nice-doesnt-have-to-be-nasty.html>.

Furthermore in October 2010, it was confirmed by the coalition government that NICE will no longer be responsible for decision-making relating to the allocation of pharmaceuticals in the NHS. In doing so, both the secretary of state for health and the parliamentary under secretary of state for quality, Lord Howe, confirmed that risk-sharing would become an underlying principle of a new value-based pricing system.⁸¹

Certainly, examples such as Velcade and Lucentis have shown that patients can gain access to drugs that would ordinarily have been unavailable because of NICE guidance. This would appear to make them attractive to policymakers. However, the UK experience of risk-sharing is still by no means encouraging. The decision to temporarily provide more expensive drugs for multiple sclerosis has so far proved flawed, with initial studies suggesting that most patients are no better off as a result of the improved access, whilst the cost of the scheme to public budgets has been estimated at £50 million annually⁸². As a result, criticisms about the scheme are intensifying and many experts are already prepared to dub it a failure, even though it still has two years left to run. Even the MS Society, the UK's largest charity for people affected by MS, has withdrawn its support for the scheme, stating that "the research element of the scheme has failed to deliver any answers as to the cost effectiveness of the drugs. Despite this, the government continues to spend money on the research".⁸³ It is still too early to make a definitive conclusion on the MS risk-sharing scheme in the UK, although it is probably safe to say that it has not gone to plan for the UK government. The MS risk-sharing scheme highlights both the experimental nature of risk-sharing as currently designed – relying on an element of trial and error – and how important it is to judge each risk-sharing mechanism on its own individual merits and flaws. While we may not be able to predict the exact future of risk-sharing within the NHS, it seems a safe assumption that risk-sharing programmes and value-based pricing will be an integral part of pharmaceutical pricing strategies.

2.5 United States

Background

Health care in the US is based on a health insurance model that is principally managed through private funding and using private provision. Private insurance is chiefly arranged and sponsored by employers, with around 52% of the American population covered by employer-sponsored insurance and just 5% covered by individual insurance.⁸⁴ Public coverage of health care is provided through Medicare, Medicaid and other programs run by both federal and state governments, which is available to the elderly, those on low income, military personnel and public employees. Around 27% of the population is covered by these public arrangements and the remaining 15% of the population is uninsured.

The pharmaceutical market in the US is predominantly market-based. Private payers, such as health insurers, managed care organisations and pharmaceutical benefit managers aggregate various health plans together and purchase pharmaceuticals on behalf of the members. These payers often employ formularies, differential cost-sharing and other methods to influence prescribing practices, allowing them to negotiate discounted prices

⁸¹ "Lansley wants 'no win, no fee' medicine" on the Spectator Coffee House blog. See <http://www.spectator.co.uk/coffeehouse/6379133/lansley-wants-no-win-no-fee-medicine.shtml>

⁸² "Multiple sclerosis risk-sharing scheme: a costly failure" (James Raftery), *British Medical Journal*, BMJ 2010;340:c1672. See http://www.bmj.com/cgi/content/full/340/jun03_1/c1672.

⁸³ MS Society, The Risk-sharing Scheme. See http://www.mssociety.org.uk/get_involved/policy_campaigns/key_issues/risk_sharing_scheme/index.html.

⁸⁴ Kaiser Commission on Medicaid and the Uninsured, "Health Insurance Coverage in the US, 2008", Kaiser Family Foundation, 2009, <http://facts.kff.org/chart.aspx?ch=477>.

from pharmaceutical manufacturers and pharmacies. Individual hospitals and other health care institutions are also increasingly using formularies to manage costs⁸⁵.

In general, risk-sharing is viewed as a recent export from Europe even though a type of risk-sharing scheme was actually negotiated in the US as far back as 1998. This was an agreement that Merck would refund both patients and insurers up to six months of the cost of Zocor (simvastatin), a statin, if the drug proved unsuccessful when combined with diet. Success for this promise was calculated on the patients' ability to lower their LDL cholesterol to target concentrations identified by their doctors. However, this arrangement appears to be more of a patient-focused marketing plan, as part of Merck's "get to goal" campaign, than a concerted attempt at risk-sharing.⁸⁶ Since then, risk-sharing schemes have begun to gain greater traction, in part due to a perceived success of European schemes. Of particular note are the following four schemes.

Examples

Oncotype DX

An agreement between UnitedHealth care and Genomic Health allowed Oncotype DX, a genetic test that can quantify the likelihood of breast cancer recurrence and predicts the likelihood of chemotherapy benefit for a large portion of early-stage breast cancer patients, to be reimbursed at list price (\$3,460 per test) for 18 months. In the meantime, both companies would track the results to decide if the genetic test was having the anticipated effect on actual clinical practice. It was decided that if the number of women receiving chemotherapy exceeded an agreed-upon threshold the insurer would receive a pre-negotiated lower price. This would occur even if the test suggested that the patients would not benefit from therapy. For the payer, this scheme opened the potential for savings from women who would have received expensive adjuvant chemotherapy, but for whom this assay suggested it is not necessary. This potential saving for each patient is calculated as approximately \$15,000, including costs associated with infusion, patient time, use of colony-stimulating factors to prevent myelosuppressive complications, and management of chemotherapy-related side effects. However, if women and their doctors choose not follow the test results and proceed with adjuvant chemotherapy, the payer receives no cost savings. In fact, they are worse off because they have also paid for a relatively expensive genomic test.

It therefore appears that UnitedHealthcare wanted to ensure that they were getting sufficient value and cost offsets to warrant the coverage and reimbursement amount for the assay by implementing an internal study on the proportion of women whose treatment choice coincides with their genetic test results. If this proportion is not in line with the agreed-upon estimates, a pricing change would then be warranted to align the reimbursement amount with the actual value received.

Januvia (sitagliptin) and Janumet (sitagliptin/metformin)

Two type II diabetes drugs, manufactured by Merck, were included in the coverage of CIGNA health care after an agreement between the manufacturer and the insurer. Uniquely, the arrangement saw drugs discounted further by a pre-agreed amount if patients' condition improved, i.e. they indicated, in aggregate, an improvement of haemoglobin A1c values indicating blood sugar levels. Rather than linking discounts to poorer performance, as common in other schemes, this does the opposite. In addition, claims data will also be used

⁸⁵ Stockholm Network, *Patient safety and comfort: the challenges of switching medicines*, 2010, p22. See http://www.stockholm-network.org/downloads/publications/Patient_Safety_and_Comfort_The_Challenges_of_Switching.pdf.

⁸⁶ Josh J. Carlson, Louis P. Garrison, and Sean D. Sullivan. "Paying for Outcomes: Innovative Coverage and Reimbursement Schemes for Pharmaceuticals", *Journal of Managed Care Pharmacy*, Vol. 15, No. 8 October 2009. See <http://www.amcp.org/data/jmcp/683-687.pdf>.

to determine if patients are taking either drug as prescribed, if so further discounts are offered to CIGNA. Finally, the agreement also saw both drugs placed more favourably on CIGNA's formulary tiers, allowing a lower copayment against other branded drugs. The focus on adherence seems to work well for all parties, with patients experiencing better outcomes, payers utilising fewer resources, and manufacturers improving sales.

This scheme by Merck distinctively offers payers their product for less money, even though it has proved its value. The reason that Merck are willing to agree to this is because they expect an improved sales volume that will offset it, which will derive from the incentives given to CIGNA to choose the Merck drugs over others.

Actonel (risedronate)

Proctor & Gamble and Sanofi-Aventis jointly sell this drug for osteoporosis and both came to an agreement with health insurer Health Alliance, which would see the drug manufacturers reimburse the cost of treating non-spinal fractures suffered by patients who consistently take their product. Rather than discounting or refunding the cost of their product, the manufacturers agree to cover the cost of treatments that would indicate their product has failed to improve a patient's condition. Hip fractures cost insurers around \$30,000 and wrist fractures cost around \$6,000, this agreement could result in a lowering of costs for Health Alliance. For the manufacturers, they are more likely to keep patients from switching to the cheaper generic versions of Fosamax (alendronate) and they are able to maintain a lower copayment level than their competitor, Boniva (ibandronate).

In this so-called Fracture Protection Pilot Program, the manufacturers showed confidence that their product will reduce non-spinal related fractures, which it was unable to show in clinical trials. The potential cost to the manufacturers of having to cover the costs of non-spinal fractures would be offset by the potential for increasing market share in a highly competitive market, whilst the payer is able to share the risk that ineffective osteoporosis treatment can lead to expensive non-spinal fractures. The scheme mirrors a similar scheme for Aclasta (zoledronate) in Italy. During the first nine months of the pilot, the reimbursement rate was 79 percent lower than the maximum outlined in the agreement and the incidence of non-spinal fractures was consistent with clinical trial data for Actonel.⁸⁷

Florida Healthy State Program (FHSP)

An interesting scheme that was agreed in 2001, initially for a two-year pilot, is the Florida Healthy State Program, which brought together Florida's Agency for Health Care Administration (AHCA) and Pfizer Inc to create a state-wide disease management program within Medicaid. Medicaid Florida is the fourth biggest public payer for low income patients in the US, with around 2.1 million beneficiaries.⁸⁸ Significant budget pressures on Medicaid Florida had reached crisis point and it was argued that better management for the health of chronically ill people would achieve a rapid reduction in their overall health care costs. Under the program, Medicaid beneficiaries with asthma, diabetes, heart failure and/or hypertension would receive support and education that could improve their health and thus lower their cost to the state for health care. The program was managed by Pfizer, who covered the costs of administration and also all medical costs in excess of mutually agreed upon "expected" costs. Florida Medicaid would be responsible for funding the

⁸⁷ "Health Alliance Announces Promising Nine-Month Results from First Ever Outcome-Based Reimbursement Program for Actonel(R) (risedronate sodium) Tablets", *PR Newswire*, see <http://www.prnswire.com/news-releases/health-alliance-announces-promising-nine-month-results-from-first-ever-outcome-based-reimbursement-program-for-actonelr-risedronate-sodium-tablets-67198367.html>.

⁸⁸ Charles D. Petrie, "Performance-based risk-sharing agreements: A US Experience" presentation at ISPOR 15th Annual International Meeting. See <http://www.ispor.org/meetings/atlanta0510/presentations/ISPOR-15th-Annual-Meeting-RTI-symposium.pdf>.

commitments up to the point agreed upon. A fixed annual budget was set, with incentives achievable if the program meets performance criteria.

Over 180,000 Medicaid beneficiaries were eligible for the program, with nearly 24,000 under active care management. Those managed demonstrated a 21% increase in medication adherence, sustained clinical improvement across four disease states managed, and reductions in overall hospitalisations and emergency room visits by 28% and 12% respectively. Overall, between 2001 and 2005, the scheme achieved \$139.5 million in savings and investment for Florida Medicaid, yet as the scheme was ultimately discontinued its successes may be better left muted.⁸⁹

Analysis

Like most risk-sharing schemes, the US examples highlight the importance of individual negotiations between pharmaceutical manufacturers and health payers. However, unlike a country such as the UK, the multiplicity of payers means that risk-sharing in the US is much more varied and involves a number of different stakeholders. It is therefore more likely that risk-sharing schemes in the US will grow as a trend rather than as a result of a policy shift, like in the UK – except maybe for Medicaid, though even this can vary from state to state.

It is clear from the US examples, that risk-sharing seems to be a means of building relationships between manufacturers and payers, in a general mutually beneficial manner. However, in the last few years risk-sharing schemes have become more popular and whilst much of the impetus for risk-sharing may have come from Europe, it is certainly not a European model that the USA are looking to emulate. However, there is still a great deal of scepticism about risk-sharing among payers in the US, particularly considering the administrative burden they entail in comparison to traditional rebates offered to pharmaceutical companies. It is also the case that some of the deals imply an element of rationing by payers, which American payers have usually been keen to avoid.

As US healthcare is traditionally not a one-size-fits-all system, it is unlikely that risk-sharing will work as a one-size-fits-all solution to rising healthcare costs. Instead, there are likely to be isolated agreements between payers and manufacturers that offer potential to deliver outcomes agreeable to both parties.

2.6 Section Summary

Among the many schemes examined in this section, it seems unclear if the objectives generally sought after in risk-sharing agreements are actually being achieved, including controlling costs, increasing patient access to medicines in a timely manner and improving the incentives for innovation. Even in examples where the objectives have been achieved, it appears that in many cases the process has not necessarily been worth the cost and time involved.

As with many cost-containment measures, it seems that the theory is much more attractive than the practice, with a wide variation in outcomes across and within different healthcare systems. Risk-sharing schemes are certainly still in their infancy and the inconsistency of success is testament to this and to the need for further experimentation. The only guarantee currently seems to be that the cost of administering, negotiating and managing such schemes is likely to remain high.

⁸⁹ Center for Health Transformation, Pfizer - Florida Healthy State Program. See http://www.healthtransformation.net/cs/pfizer_florida_healthy_state_program.

Nevertheless, generally there are two prevailing motives that have affected the different risk-sharing agreements studied here.

The first is price, which is usually the sole concern of the payer. In almost all the risk-sharing agreements looked at in this study the concern as to price of a pharmaceutical has come from the payer. With this in mind two mechanisms tend to form. The first is a cost cap, which can be imposed either on a per patient or annual cost basis. This cost cap can usually provide a handy guarantee for the payer that costs will not escalate uncontrollably and fits comfortably in government annual budgets, which usually exist on a “make ends meet” basis. Discounts are often used as a way of maintaining a cost cap, or indeed as way of creating one. The second mechanism is a price rebate. Here, the price agreed before at the outset of a deal is conditional and thus can be lower on the basis of certain conditions, usually based on performance, or indeed it could be expected that the product be reimbursed by the manufacturer entirely.

The second prevailing motive for entering risk-sharing agreement is performance, which is usually the concern of the manufacturer who, whilst having faith in their product, will be concerned if it is seen not to have performed adequately. As a result, pharmaceutical effectiveness is usually monitored as a mechanism for proving its performance. Again, this of course is not exclusively a preserve of the manufacturer, as very often payers will be keen to monitor the success of a drug to ensure that the access provided is correct. An additional mechanism stemming from the desire to highlight a product's performance is compliance management. Compliance can be a big risk factor for manufacturers who are interested in proving the performance of their products. After all, one of the many reasons why drugs may work in clinical trials and not in the real world is because compliance by the patient is not maintained.

Below is a table that attempts to summarise each of the risk-sharing agreements highlighted in this study. In addition, the right hand columns of the table indicate which mechanisms are in place as part of the agreement. Four mechanisms are identified, as outlined above, two motivated by price (cost caps and rebates) and two motivated by performance (patient monitoring and compliance management). As the table suggests, almost all schemes have been motivated by price in some way, one of the few exceptions appears to be a deal for Tracleer that was provided for a very small section of the population and thus had few cost risks. As a motivation mainly of payers, it is unsurprising that this is the case, as it is payers who usually hold most of the cards when it comes to entering risk-sharing negotiations. In terms of the mechanisms motivated by performance, it appears that patient monitoring is the most common, whilst agreements that use compliance management are limited to only a handful, mostly in the US.

Table 5: Summary of risk-sharing agreements in Australia, Germany, Italy, UK and the US

	Intended for	Country	Year	Manufacturer	Payer	Price		Performance	
						Cost caps	Rebate	Monitor	Compliance
Enbrel	Rheumatoid arthritis	Australia	2003	Wyeth	Medicare Australia	✓	✗	✓	✗
Tracleer	PH	Australia	2004	Actelion	Medicare Australia	✗	✗	✓	✗
Aclasta	Osteoporosis	Germany	2007	Novartis	DAK and BEK	✗	✓	✓	✗
Sandimmune	Organ transplants	Germany	2007	Novartis	DAK and BEK	✗	✓	✓	✗
Myfortic	Organ transplants	Germany	2007	Novartis	DAK and BEK	✗	✓	✓	✗
Certican	Organ transplants	Germany	2007	Novartis	DAK and BEK	✗	✓	✓	✗
Avastin+Taxol	Breast/kidney cancer	Germany	2007	Roche	Several	✓	✓	✓	✗
Enbrel	Rheumatoid arthritis	Germany	2008	Wyeth	Tanus BKK	✗	✗	✗	✓
Tarceva	Lung cancer	Italy	2006	Roche	SSN	✓	✗	✗	✗
Sutent	Kidney cancer	Italy	2006	Pfizer	SSN	✓	✗	✗	✗
Nexavar	Kidney cancer	Italy	2006	Bayer	SSN	✓	✗	✗	✗
Sprycel	Leukaemia	Italy	2007	BMS	SSN	✓	✗	✗	✗
Avastin	Various cancers	Italy	2008	Roche	SSN	✓	✗	✗	✗
Tasigna	Leukaemia	Italy	2008	Novartis	SSN	✗	✓	✓	✗
Nexavar	Liver cancer	Italy	2008	Bayer	SSN	✗	✓	✓	✗
Aclasta	Osteoporosis	Italy	2009	Novartis	SSN	✗	✓	✓	✗
Avonex	Multiple sclerosis	UK	2002	Biogen Idec	NHS	✓	✓	✓	✗
Rebif	Multiple sclerosis	UK	2002	Merck Serono	NHS	✓	✓	✓	✗
Betaferon	Multiple sclerosis	UK	2002	Schering AG	NHS	✓	✓	✓	✗
Copaxone	Multiple sclerosis	UK	2002	TEVA/Aventis	NHS	✓	✓	✓	✗
Velcade	Multiple myeloma	UK	2007	Johnson&Johnson	NHS	✓	✓	✓	✗
Lucentis	“Wet” AMD	UK	2007	Novartis	NHS	✓	✗	✓	✗
Oncotype DX	Breast cancer	USA	2007	Genomic Health	UnitedHealthcare	✓	✓	✓	✗
Januvia	Diabetes	USA	2009	Merck	CIGNA	✓	✗	✓	✓
Janumet	Diabetes	USA	2009	Merck	CIGNA	✓	✗	✓	✓
Actonel	Osteoporosis	USA	2009	P&Gamble/Sanofi	Health Alliance	✗	✓	✗	✓
Healthy state	Disease management	USA	2001	Pfizer	Medicaid Florida	✓	✓	✓	✓

This table summarises 27 risk-sharing agreements highlighted in this study. The right hand columns indicate the mechanisms that are in place as part of the agreement, four mechanisms are identified.

The two mechanisms to the left are motivated by an interest in the pharmaceutical’s price, these are **cost caps** and **rebates**.

The two mechanisms to the right are motivated by an interest in the pharmaceutical’s performance, these are **patient monitoring** and **compliance management**.

Section 3: Conclusion and Policy Recommendations

When it comes to medicines, risk-sharing agreements can mean a number of things to different parties. However, they should mainly be seen as a way to facilitate the common goal of bringing new medicines to the market and making the right decisions about financing these medicines from the public purse.

Both payers and manufacturers fundamentally agree on the benefit that greater access to new treatments provides to patients, which is why risk-sharing schemes are considered in the first place. This, however, does not make risk-sharing schemes any easier to negotiate or, indeed, make risk-sharing a “no-brainer” when it comes to providing expensive treatments to patients.

The pitfalls of risk-sharing schemes have been laid bare in this study: time-consuming negotiations, costly administration, difficulty in assessing success and over-complicated arrangements are just a few. However, in many cases the failure of the scheme has not necessarily been down to an inadequacy of the pharmaceutical product itself, but rather a “malfunction” in the design of the risk-sharing agreement. As a result, it is usually very difficult to predict if a risk-sharing scheme will work or whether it will fail, allowing for inconsistent results. There is, as yet, no gold standard for risk-sharing agreements, nor is there ever likely to be one.

One of the main reasons why risk-sharing schemes have been so difficult to implement, despite the fundamental consensus as to why they are important, is because they have been used for motives aside from purely providing patient access. In many instances, payers have seen risk-sharing as a tool for bringing down health care budgets, which many policymakers maintain is due to high spending on pharmaceuticals. As such, risk-sharing is not an innovative concept but rather a continuation of a cost-containment approach seen in pricing and reimbursement systems more generally.

However, as discussed in this paper, if policymakers see risk-sharing as a “golden bullet” for driving down costs, they are mistaken. Using risk-sharing as a convenient fig leaf for cutting pharmaceutical prices undermines the potential for creating a true concept of risk-sharing, whereby payers and manufacturers work together to distribute risk between them for the public good.

Such a concept would rightly acknowledge the constraints on both payers, who have finite resources to spend on healthcare, and manufacturers, who must recoup the investments they have made to bring the product to market.

Payers should acknowledge that risk-sharing agreements need to genuinely factor in the efforts and risks associated with the development of new medicines, as well as the regulatory, financial and commercial risk of managing these medicines once they have reached the market. Manufacturers need to acknowledge the fact that risk-sharing agreements may require them to share the burden of providing more information about the efficacy of their medicines and, at times, even to share the burden of financing these medicines. The latter may be relevant to cases in which the medicine may have proven to be less cost effective than was initially anticipated or if it has been used and prescribed in greater quantities, thus resulting in a “financial gap” between estimated budgets and allocated ones.

However, most importantly, risk-sharing agreements should reflect a true commitment to serve the needs of patients, to allow for greater individual choice, while securing the most effective methods of treatments.

This means that the risk may be at the expense of payers, or manufacturers or both - but never at the expense of patients.

In order to protect this principle a number of recommendations are provided below.

- We need to accept that risk-sharing is still in its infancy and that current experiences are by no means a basis for widespread use. When drugs are rejected for reimbursement, a risk-sharing scheme can act as a band-aid over the damage, yet this is not a sustainable system for the future.
- A pre-condition for the creation of an effective risk-sharing agreement is to understand what were the specific reasons for including, or not including, a certain drug for reimbursement. These reasons provide the basis upon which risk-sharing arrangements may be created.
- Risk-sharing schemes need to adequately address both price and performance concerns. Current examples seem to suggest that the former is dictating the mechanisms by which risk-sharing schemes work and that, to this extent, risk sharing agreements aim to control the issue of cost rather than to deal with the issue of risk.
- Risk-sharing agreements are a means to an end. If the primary intention is providing greater access to the best available treatments within finite budgetary frameworks then risk-sharing should be considered as part of a wide range of policies aimed at serving this objective.