



WHICH PRICE IS RIGHT?

Regulating the cost of pharmaceuticals in Europe
and North America

By Paul Healy

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By Paul Healy, Stockholm Network

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Executive Summary

Unabated rises in health spending are threatening to push healthcare systems to their limit. The cause of these increases is a combination of shifting demographics and an escalation in the cost of providing medical treatments. At present, policymakers appear keener to focus on the latter, since they are mostly powerless to do much about the former. Yet in doing so, they have tended to focus their cuts mostly on the cost of pharmaceuticals.

In most developed countries, spending on pharmaceuticals represents around 16% of total spending on health. Certainly, this is no small amount but OECD data suggests that contrary to what is commonly assumed, more recent increases in health spending are not necessarily caused primarily by increases in spending on pharmaceuticals. In fact, since 2005 the contribution towards total increases in health spending accurately attributed to pharmaceuticals is 17.3% in Canada, 13.8% in France, 15.1% in Germany, 5.6% in Italy, 14.0% in Spain, 5.4% in the United Kingdom and 10.9% in the United States.¹ While real-term rises in pharmaceutical spending should not be ignored, it indicates that focusing on pharmaceutical expenditure alone is unlikely to achieve significant cost savings. Although it may be more convenient and less politically sensitive, particularly in European systems where the government is often the main purchaser of such products, patients are likely to derive greater benefit from a holistic approach to cost-containment.

The current approach has seen the development of regulations around the prices that manufacturers may set for their pharmaceutical products. These are regulations separate to the appropriately robust controls around the manufacture and licensing of medicines, which are justified by the harm that could arise from unregulated access to medicines. Price regulations are designed to contain pharmaceutical costs by allowing health authorities to control prices. These regulations are mostly enforced in a heterogeneous way across the developed world, with different approaches reflecting distinct national policy priorities. The consequence can be an artificial price differentiation for pharmaceuticals between countries that reflects each government's willingness to pay for pharmaceuticals or more accurately their desire to get a "good deal" from pharmaceutical manufacturers. The consequence can be a race to the bottom between contending payers who seek to force low prices upon manufacturers with little consideration of the market within which they are being employed. Such rent-seeking is particularly apparent within the

¹ Health Data 2010 – Frequently Requested Data, Total expenditure on health/capita, US\$ purchasing power parity, and Total expenditure on pharmaceuticals and other medical non-durables/capita, US\$ purchasing power parity.

European Union where prices for pharmaceuticals vary wildly, by up to 25%, regardless of a common market with relative similarity in demand and sensitivities.

In attempting to understand this price differentiation, it is possible to identify a pricing spectrum that has developed as a result of payers' attempts to establish what they deem to be fair prices. This spectrum ranges between the prices that are established within a controlled pricing environment by payers and the prices that are established within a market-based pricing environment by manufacturers. Whilst very few systems can be accurately described as absolutely controlled or absolutely market-based, most systems can be located somewhere on the spectrum. The idea that some sort of perfect price can be agreed through this process is unrealistic, particularly given the current healthcare and economic environment.

The controlled pricing end of the spectrum showcases a number of different mechanisms, most of which are designed to control pharmaceutical prices from the supply side, for example, through price negotiations, profit controls and cross-country comparisons. There are also price controls from the demand side, such as internal referencing. In all of these, payers are ultimately establishing a "controlled price", which reflects the value of a pharmaceutical as well as the need to contain costs. In market-based pricing, pharmaceuticals are priced based more closely according to the fluctuation of market conditions. Whilst manufacturers are still required to oblige with all the relevant safety, efficacy and quality requirements, when it comes to pricing they are able to establish a more or less "market-based price" for their product.

What becomes apparent when studying this pricing spectrum is that market-based pricing encourages greater medical innovation, by expanding the incentives for manufacturers to invest in research and development. This is no more evident than in the United States, which is the most profitable and productive pharmaceutical market by far. Yet, the drawback for this innovation appears to be higher pharmaceutical prices, which is perhaps unsurprising given that most price regulations are designed to bring prices down. As a result, it can reasonably be asserted that the US is getting "more for more" when comes to its approach to pharmaceutical pricing. Europe, on the other hand, is getting "more for less", given the extent of innovative products being imported from freer markets such as the US.

Although it may not seem so initially to European policymakers, this is ultimately problematic. Firstly, it puts European nations in a position where they can be accused of "free-riding" on patients in the US and thus not paying their fair share towards the current cost of developing medicines that are of value to the entire globe, not least to their own patients. Secondly, it means that European nations have surrendered

some autonomy over their healthcare systems by placing the burden for medical innovation on the shoulders of others, whilst leaving themselves susceptible to changes in pharmaceuticals regulations over which they have no authority.

Pricing policy should not be a race to the bottom. Whilst payers do have a duty to manage their budgets in an effective manner, they should take care when contemplating price controls and consider them as part of an overall approach, which understands the efficiency of healthcare systems in a dynamic way. Short-term measures to reduce pharmaceutical prices artificially are, firstly, unlikely to deal with rising healthcare budgets but are also likely to hamper innovation further down the road.

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Introduction

Many healthcare systems are now beginning to face the growing challenge of providing patients with continued access to high-quality health services, in spite of rising costs and a declining active workforce. Certainly, this is nothing new and plenty of studies have contended as much, calling for greater urgency from policymakers in tackling such challenges. Most have responded by introducing reforms that focus on reining in costs to establish more contained healthcare budgets, which would be less reliant on routine real terms funding increases. Unsurprisingly, pharmaceuticals, which in most developed countries represent around 16% of healthcare costs, have been identified as part of this strategy and the result is price regulations that aim to control the price of pharmaceuticals.

Regulations in the pharmaceutical field are generally agreed to provide patients with the assurance that medicines consumed are safe and effective, whilst ensuring that dependence on them is not being exploited to unfairly reduce healthcare budgets. Yet, some regulations are proving to be particularly cumbersome and may actually be obstructing patients from accessing effective medicines in the short-term, whilst possibly threatening medical innovation in the long-term. This paper studies pharmaceutical price regulations and analyses what future role they should play in modern healthcare systems.

It begins by further defining the challenge of unsustainable healthcare systems, identifying the need to secure value for money in healthcare budgets. In doing so, it attempts to put pharmaceutical spending in perspective and confronts a widely-held view that the main cause of healthcare spending growth is increased pharmaceutical costs. This leads into a discussion about the evolution of cost-containment strategies pursued by policymakers and the development of pharmaceutical price regulations as a result. Price differentiation, which is caused by heterogeneous regulations, is then considered and potential negative side-effects are documented.

The paper then moves on to examine the relationship between healthcare payers and pharmaceutical pricing, identifying a distinction between public and private arrangements. It contends that whilst all payers have a duty to manage healthcare budgets efficiently, it is interesting to see how financing can affect the tenacity of payers when regulating pharmaceutical prices. In particular, two key payer functions are explored, i.e. prioritising treatments and securing innovation, in order to ascertain the effect that financing has on how these are pursued. In doing this, the paper is able to establish the theoretical groundwork upon which a more empirical analysis of price regulations can be developed. Such analysis is concentrated

around the notion of a pricing spectrum, in which policymakers and manufacturers attempt to balance between the limits of controlled and market-based pricing in order to establish what they believe to be a fair price.

Controlled pricing is explored first and our analysis highlights how regulations are utilised by payers in order to obtain a controlled price for pharmaceuticals, in line with cost-containment objectives. Many tools are used to assist payers in this process and the paper discusses four different mechanisms: price negotiations, profit controls, cross-country comparisons and internal referencing. By contrast, under market-based pricing, pharmaceutical prices are set by manufacturers. The factors that may determine this price are then identified and explained. Drawing on the experience of the United States, it is argued that market-based pricing can allow for greater investment into pharmaceutical research and development, which can contribute to a more intense level of innovation. However, such benefits tend to entail higher pharmaceutical prices, as is the case in the United States, which is “getting more for more”. Within the current global pharmaceutical market, more market-based pricing in the United States is driving global medical innovation but Americans consumers are paying more as a consequence, confirming that Europe is, on the other hand, “getting more for less”. This “free-riding” is problematic, given that the development of medical innovation is a global responsibility and should not depend purely on one set of national taxpayers.

Finally, the paper offers conclusions and suggests recommendations for pharmaceutical price regulations towards securing the ultimate objective of more effective and financially sustainable healthcare systems.

The Challenge of Unsustainable Healthcare

It is now generally accepted in the developed world that many healthcare systems, as they currently stand, will struggle to remain financially sustainable in the future. Unabated rises in demand for health services are threatening to push healthcare spending above – and even beyond – its limits. Indeed, a multitude of recent healthcare reforms in a number of countries have been presented on this basis.

President Obama's health reforms in the United States, which became law in March 2010, were prompted by the belief that the healthcare system was "placing an unsustainable burden on taxpayers".² The President remarked that "If we do nothing to slow these skyrocketing costs, we will eventually be spending more on Medicare and Medicaid than every other government program combined. Put simply, our healthcare problem is our deficit problem."³ Health reforms in Germany, passed in November 2010 by the Bundestag, warned that the German healthcare system would struggle to maintain performance and quality without reforms to make funding more "sustainable and socially equitable".⁴ It identified that in 2011, the healthcare deficit was expected to reach €11 billion and that, as a result, rising health insurance premiums would "increase the costs of wages and jeopardise jobs".⁵ Prospective United Kingdom health reforms, presented to parliament in January 2011, promised to put the National Health Service (NHS) on "a more sustainable and resilient financial footing".⁶ The proposals identify how "since its inception, the NHS budget has risen by an average of over 4% in real terms each year" and that even with a commitment to increase health spending in real terms for the following five years "the NHS will face a sustained and substantial financial constraint."⁷

Shifting demographics

One widely agreed reason why healthcare systems are becoming unsustainable is shifting demographics, which are gradually ballooning population pyramids. The pyramids shown below (see page 12) provide an example, in the United States, of how populations have changed over the last thirty years and are set to change for the next thirty years. It shows that a much larger percentage of the population was aged between 20 and 40 years old (when people tend to work more and use health services less) in 1980 than in 2010 and also what is expected in 2040. It also shows that there is a bigger percentage of the

² White House (2009) - Remarks by the President to a Joint Session of Congress on Health Care.

³ *Ibid.*

⁴ Bundestag (2010a) - Beschlussempfehlung und Bericht des Ausschusses für Gesundheit, p. 2.

⁵ Bundestag (2010b) - Entwurf eines Gesetzes zur nachhaltigen und sozial ausgewogenen Finanzierung der Gesetzlichen Krankenversicherung, p. 2.

⁶ Department of Health (2010). *Equity and excellence: Liberating the NHS*, p. 45.

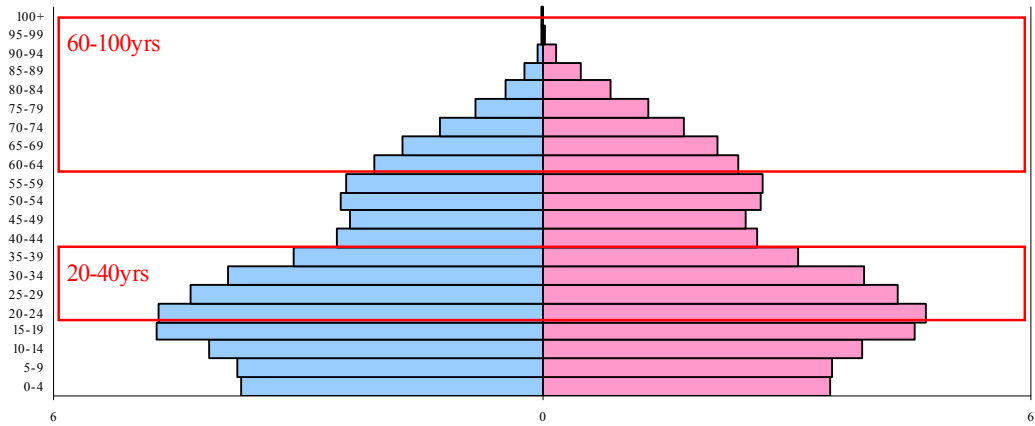
⁷ *Ibid.*, p. 43.

population aged between 60 and 100 years old (when people tend to work less and use health services more) in 2010 than there was in 1980, with this trend likely to become much more pronounced by 2040. The consequences of this for healthcare cannot be underestimated. It means that there will be less people working to pay for health services and at the same time more people reliant on using them. This same trend is seen in population pyramids in most other developed countries.

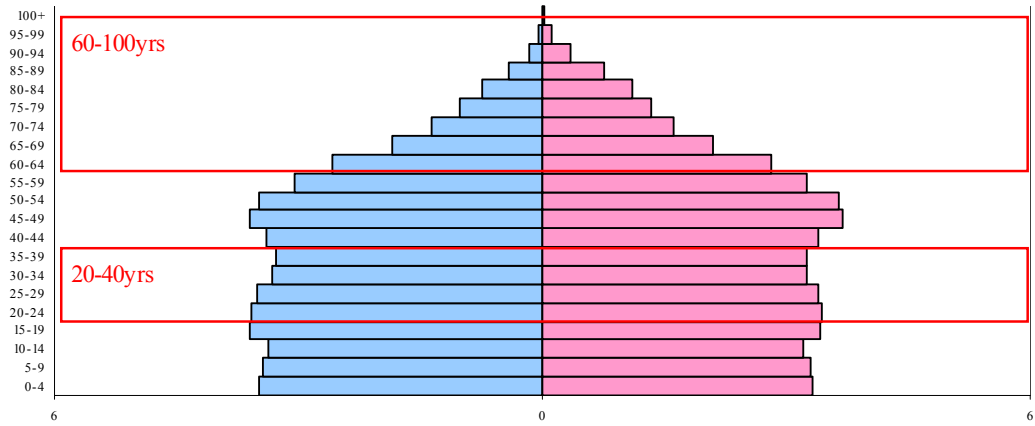
One of the main causes of these demographic shifts, aside from an exceptionally high birth rate of “baby boomers” in Europe and North America between 1946 and 1964, has been the development of healthcare systems that are now able to keep patients alive for longer. Since 1961, life expectancy at birth has increased in the most developed countries in Europe and North America by over 10 years.⁸ This ability of developed healthcare systems to increase their citizens' lives has been a double-edged sword that has borne dividends in recent years, allowing “baby boomers” to work and finance healthcare systems longer, yet is soon set to swing back when the same people inevitably require the health services that their age demands. This trend is already being seen and, as a consequence, healthcare payers have often relied on a gradual accumulation of debt obligations to tide over healthcare budgets. Such debt is not necessarily unsustainable in itself, yet if demand is expected to get much more burdensome, then it is difficult to see how deficits can be reduced even at the top of the economic cycle.

⁸ Life expectancy in Canada, United States and the EU5 (France, Germany, Italy, Spain and United Kingdom) has increased by on average 10.2 years since 1961. See OECD (2010). Health Data 2010 – Frequently Requested Data, LE Total Population at birth.

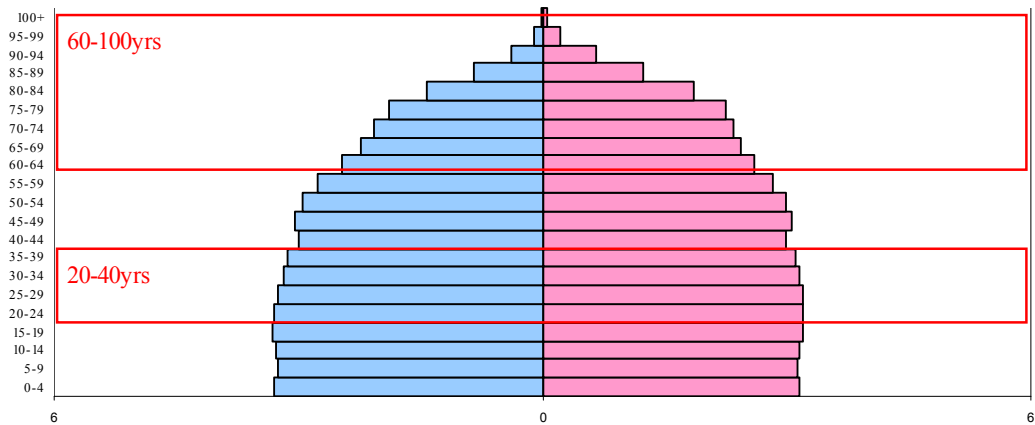
US 1980 Population Pyramid



US 2010 Population Pyramid



US 2040 Population Pyramid



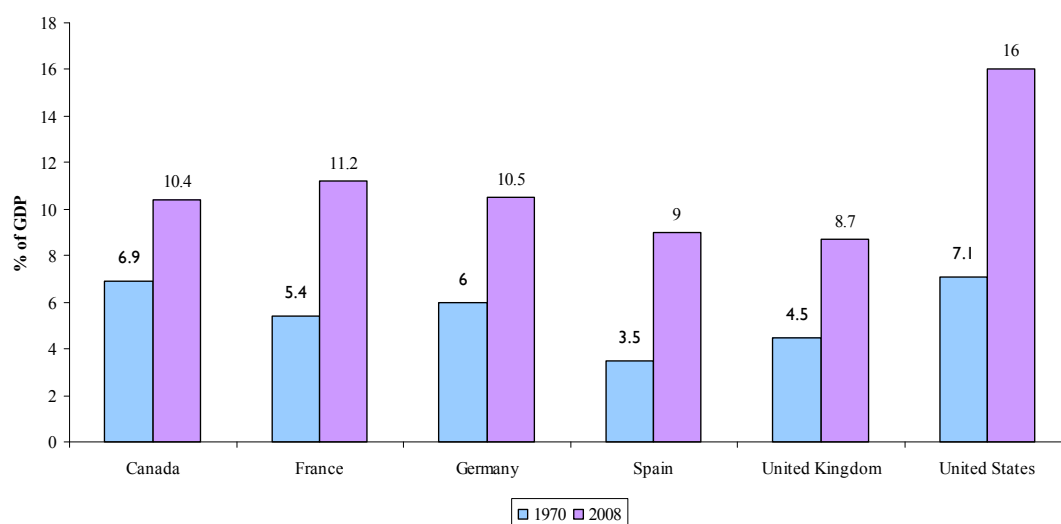
Source: US Census Bureau (2010)⁹

⁹ Calculated from US Census Bureau (2010). See <http://www.census.gov> (Accessed on 20 Apr. 11).

Containment costs

With this in mind, policymakers are compelled to find ways to control health spending. On average, current health spending per capita in the most developed countries is 18 times the amount that it was in 1970.¹⁰ As a percentage of GDP, health spending has also grown considerably since 1970 and the graph below shows the increase in health spending from 1970 to 2008. If this trend were to continue at the same rate of increase for the next 40 years in the United States, for example, by 2050 health spending could be around a fifth of the country's GDP.

Health spending, as % of GDP, in 1970 and 2008



Source: OECD Health Data (2010)¹¹

So, in the pursuit of lower healthcare costs most policymakers have turned their attention to the amount of money that is spent on pharmaceuticals. This is understandable as pharmaceutical spending, on average in the most developed countries, represents around 16% of the total spending on health, which is a significant portion of healthcare budgets.¹² It is also less politically problematic and a more visible expenditure for policymakers to confront than non-pharmaceutical healthcare costs, such as services and salaries.¹³ Yet, data suggests that the burden of pharmaceutical spending on current healthcare budgets is actually decreasing in some countries even though healthcare spending continues to grow. Take the

¹⁰ Health spending per capita in Canada, United States and the EU4 (France, Germany, Spain and United Kingdom) has increased by on average 1872.82% from 1970 to 2008. See OECD (2010). Health Data 2010 – Frequently Requested Data, Public expenditure on health/capita, US\$ purchasing power parity (Figures for Italy from 1970 were unavailable and so excluded).

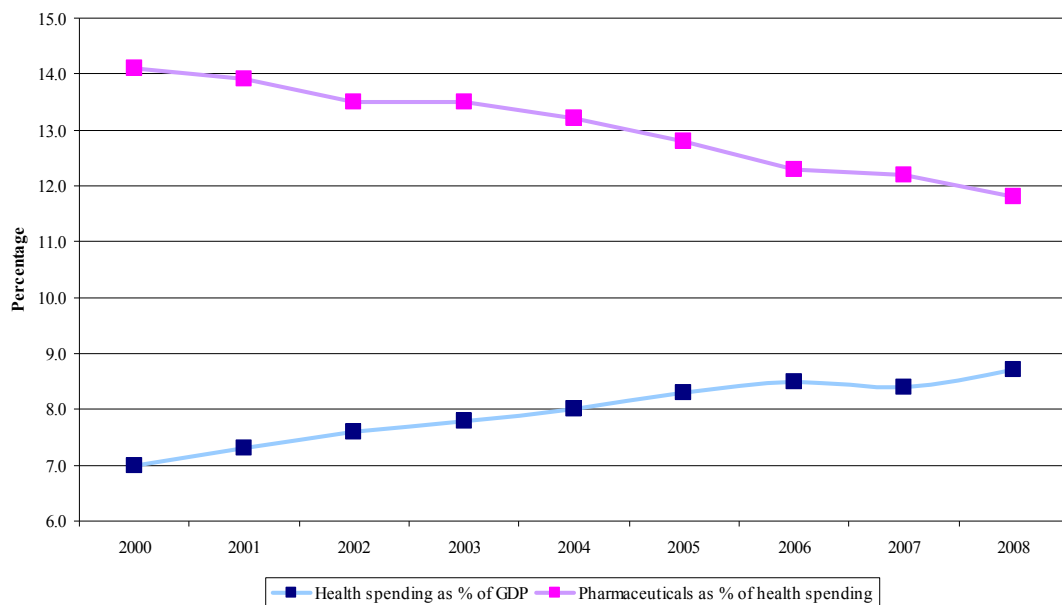
¹¹ *Ibid*

¹² Pharmaceutical spending, as a percentage of health spending, in Canada, United States and the EU5 (France, Germany, Italy, Spain and United Kingdom) is 15.9% in 2008. See OECD (2010). Health Data 2010 – Frequently Requested Data, Total expenditure on pharmaceuticals and other medical non-durables, % total expenditure on health.

¹³ Mrazek, Monique (2002). "Comparative Approaches to Pharmaceutical Price Regulation in the European Union" in *Croatian Medical Journal* (Vol. 43, No. 4), p. 453.

United Kingdom since 2000 for example, as shown in the graph below. We can see that health spending, as a percentage of GDP has increased between 2000 and 2008, yet during that same period pharmaceutical spending, as a percentage of all health expenditure, has decreased year on year.

UK health spending, as % of GDP (lower blue line) and UK pharmaceutical spending, as % of total health spending (upper purple line), between 2000 and 2008



Source: OECD Health Data (2010)¹⁴

What this shows is that whilst pharmaceutical spending in the United Kingdom has increased in real terms between 2000 and 2008 (from \$260 per capita to \$368), when this is compared with real terms increases in total health spending (from \$1,837 per capita to \$3,129), the proportion owing to increased pharmaceutical costs is 8.3%. In fact, pharmaceutical costs as a percentage of the total increase in health spending has been even less since 2005 (5.4%) and in 2008 represented just 2.16% of total United Kingdom health cost increases.¹⁵ Similar trends are seen in the other developed healthcare systems. Since 2005, pharmaceuticals as a percentage of total increases in health spending represented 17.3% in Canada, 13.8% in France, 15.1% in Germany, 5.6% in Italy, 14.0% in Spain and 10.9% in the United States.¹⁶

Although this is not to suggest that real term rises in pharmaceutical spending should be ignored, it is offered to policymakers as an indication that focusing on pharmaceutical expenditure alone is unlikely to

¹⁴ *Ibid.*

¹⁵ Health Data 2010 – Frequently Requested Data, Total expenditure on health/capita, US\$ purchasing power parity, and Total expenditure on pharmaceuticals and other medical non-durables/capita, US\$ purchasing power parity.

¹⁶ *Ibid.*

achieve significant cost savings. Whilst it may be more convenient and less politically sensitive, particularly in systems where the government is the main purchaser of such products, patients are likely to benefit more from a holistic approach to cost-containment.¹⁷

Price regulation and differentiation

The most common and direct way that pharmaceutical costs are contained is through price regulations, which allow health authorities to control the prices that are set for pharmaceutical products. Generally, these regulations are enforced in a heterogeneous way across the developed world, with different approaches reflecting distinct national policy priorities within the historical and cultural context of the healthcare system.¹⁸ This has prompted the WHO to describe such processes as an “unpredictable lottery” because manufacturers of pharmaceuticals are obliged to bring products to market with little or no indication as to the prices that will be set for them.¹⁹ Not only the WHO, but also the European Commission has flagged up concerns about the unpredictability of pharmaceutical pricing policies that target short-term policy needs and limit competition by fixing prices.²⁰ Certainly, national pricing regulations seem to be prone to erratic changes and they will often add an unwanted hurdle to pharmaceutical manufacturers who may have only just managed to navigate efficacy, safety and quality requirements.²¹

The consequence can be an artificial price differentiation for pharmaceuticals between countries that is not necessarily logical. Indeed, price differentiation in itself is not a problem. After all, sellers will often need to price their products differently in some markets to reflect the relative sensitivities of the market that they are being sold in.²² However, pharmaceutical price differentiation in the developed world seems rather to reflect a government’s willingness to pay for pharmaceuticals or more accurately their desire to get a “good deal” from pharmaceutical manufacturers. The consequence can be a race to the bottom between contending payers that seek to force low prices upon manufacturers with little consideration of the market within which they are being employed. Such rent-seeking is particularly apparent within the European Union where prices for pharmaceuticals vary wildly, by up to 25%, regardless of the relative similarity in demand and sensitivities of respective markets.²³

¹⁷ Cueni, Thomas (2008). “Can Europe afford Innovation” in *Eurohealth* (Vol. 14, No. 2), p. 9.

¹⁸ Mrazek (2002) p. 453.

¹⁹ WHO (2004). *Priority Medicines for Europe and the World*, p. 104.

²⁰ Mrazek (2002), p. 453.

²¹ Cueni (2008), p. 8.

²² Ridley, David (2005). “Price Differentiation and Transparency in the Global Pharmaceutical Marketplace” in *Pharmacoeconomics* (Vol. 23, No. 7), p. 652.

²³ “Drug prices across the EU vary by up to 25%; study” in *PharmaTimes* (27/05/11).

Robust regulation of the manufacture and licensing of medicines is justified by the harm that could arise from unregulated access to medicines. Yet, inflexible regulations that generate artificially low prices can actually delay and hinder access to effective medicines, which in itself seems counterproductive.²⁴ With this in mind, it is interesting to note that only one-third of marketed prescription pharmaceuticals from one of the seven largest drug markets (Canada, France, Germany, Italy, Japan, United Kingdom and United States) are also marketed in the other six, with price regulations having a large bearing on launch patterns.²⁵

²⁴ Pfister, Lukas (2009). "Drug development: a complex and risky but potentially rewarding collaborative process" in *Eurohealth* (Vol. 15, No. 4), p. 9.

²⁵ Kyle, Margaret (2007). "Pharmaceutical Price Controls and Entry Strategies" in *The Review of Economics and Statistics* (Vol. 89, No. 1), pp. 88, 98.

Payers and Pricing

To get a better understanding of pharmaceutical price regulations, it is important to first examine the relationship between payers and pharmaceutical pricing. Payers provide insurance for patients who are often unable to risk purchasing treatments as and when they need them because of the potential for unexpectedly high costs. As a result, the risk to an individual patient is pooled with other patients so that contributions from healthier individuals can help fund treatments to the less healthy. To manage this, payers will usually decide for their patients which services they are willing to cover within their insurance scheme. This is because healthcare budgets are not infinite and the executors of such budgets have an obligation to those covered to ensure that finances are managed in a sustainable, appropriate way.

In theory, the ultimate motive is to prevent healthcare budgets exceeding affordable levels and thus going bust. When a payer finds itself insolvent, such as is seen currently in Greece, this can often result in patients being deprived access to health technologies, as medicinal supplies run low because of the absence of funds.²⁶ Such shortfalls can of course occur in the most developed healthcare systems, although many payers could always attempt to cover increased costs, in public systems, by raising taxes or, in private systems, by raising premiums. Both these measures though will ultimately have a negative effect on wages, increasing the cost of working, weakening competitiveness and limiting the amount that workers have to spend into the economy.²⁷ Therefore, all payers have a duty to control healthcare budgets, not just to keep the system functioning, but to also prevent it from becoming a strain upon the overall economy.

Public and private

In many cases individuals may not possess the necessary knowledge or information to make choices between similar treatments and services and so are content with third-party payers doing this for them. This is because many developed healthcare systems have payers that are in fact single, publically-funded bodies who purchase services using public budgets. These public budgets are financed by mandatory contributions paid by citizens, either through taxation or social insurance. An alternative is to have a system in which patients pay individually to competing private health insurance companies, which are contractually obliged to provide previously agreed health services. In such a system, patients tend to be liable only to fund the services that they desire and so can often reduce their contributions by excluding

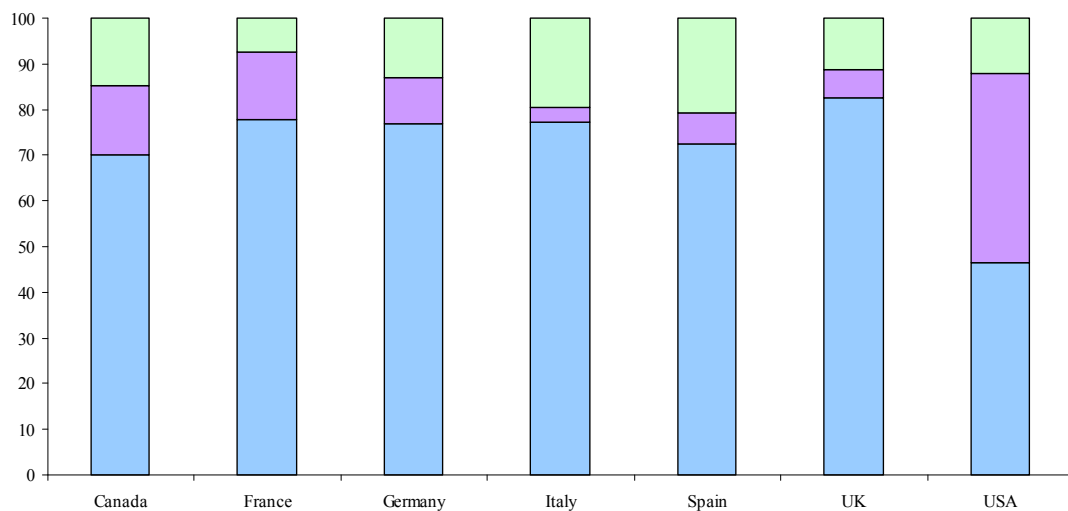
²⁶ "Greece fails to pay medical bills" in *Financial Times* (22/05/11).

²⁷ Gerlinger, Thomas (2010). "Health Care Reform in Germany" in *German Policy Studies* (Vol. 6, No. 1), p. 111.

treatments that they either feel unlikely to need or prefer not to use.²⁸ There are also some social insurance systems, particularly in Europe, which utilise multiple private payers, yet employ government intervention and public subsidies to ensure universal coverage and determine benefit packages.

The decision about how best to utilise public and private payers is a matter of societal choice and the graph below gives an indication as to the balance between public and private spending in Europe and North America. It shows that only in the United States does spending from private sources account for more than public spending. This is because private health insurance companies pay for many health services on behalf of their customers, who are charged a regular premium, mainly through their employer, for coverage. However, despite this, public payers in the United States still play an influential, albeit fragmented, role. Health insurance products funded by the United States government could, in fact, cover up to 120 million people.²⁹ The graph also shows the reliance of health services in the United Kingdom on financing from a single public body, the National Health Service (NHS), whilst most other countries seem to make greater use of private contributions, either through insurance or out-of-pocket payments, which are generally used to supplement the basic level of care offered by the public payers.

Public (blue), private (purple) and out-of-pocket (green) expenditure on health



Source: OECD Health Data (2010)³⁰

This distinction between public and private payers is important because it seems to have an effect on the pricing of pharmaceuticals. In particular, a pharmaceutical in public payer systems is only ever likely to reach the patient if it is reimbursed by the public payer. This reinforces the monopsony of the payers in

²⁸ Oliver, Adam (2009). "The Single-Payer Option: A Reconsideration" in *Journal of Health Politics, Policy and Law* (Vol. 34, No. 4), p. 524.

²⁹ Harvard Kennedy School (2007). *Health Care Delivery Covered Lives – Summary of Findings*, p. 3.

³⁰ OECD (2010). Health Data 2010 – Frequently Requested Data, Public expenditure on health, % total expenditure on health.

the market and allows them to negotiate lower prices with manufacturers, who have no other means for market access.³¹ Furthermore, the concentrated revenue stream available to public payers allows them to better secure trade-offs between costs and quantity.³² Yet, patients within public payer systems can also find that their choice is limited as they too are reliant on the public payer for reimbursement in order to obtain access. This in itself will weaken the capacity for competition, which could have driven down prices anyway.³³

To better understand the role of payers in pricing pharmaceuticals, it is important to consider two key functions that a payer would be expected to fulfil. The first is their responsibility for prioritising medical treatments and allocating resources accordingly, whilst the second is their obligation to ensure a continual supply of the most up-to-date technologies and treatments in the long-term through medical innovation.

Prioritising medical treatments

The prioritisation of medical treatments and services occurs now in most healthcare systems and is important for payers to be able to effectively manage their budgets to ensure that they are sustainable. It is unrealistic to expect payers to be able to fund every treatment and service to every patient and so it is understandable that payers now choose to allocate resources towards guaranteeing the most effective treatments, potentially at the expense of less-effective ones. In general, payers are able to prioritise treatments by either limiting the supply or by tempering the demand for certain products.

In tempering the demand, some payers can impose co-payments that require patients to pay something towards the costs of some treatments, whilst one-off user charges can also be required when accessing certain services, such as GPs. There is some evidence to show that when patients are made aware of the costs of health services, they are provided with an incentive to forgo those services that are not really necessary, whilst allowing for cost-sharing if they are.³⁴ Private payers will often use these measures to maintain lower regular premiums and so patients will be acutely conscious of the benefits that cost-sharing may provide them. However, in public systems it is harder for payers to implement them due to the perception that services should be available “free at the point of entry”, funded entirely by taxation.³⁵ It is widely debated if user charges or co-payments are effective at reducing demand, or indeed sharing

³¹ Hutchings, Adam (2010). “Rewarding innovation? An assessment of the factors that affect price and reimbursement status in Europe” in *Journal of Medical Marketing* (Vol. 10, No. 1), p. 83.

³² Gled, Sherry (2009). “Single Payer as a Financing Mechanism” in *Journal of Health Politics, Policy and Law* (Vol. 34, No. 4), p. 596.

³³ Oliver, Adam (2009). “The Single-Payer Option: A Reconsideration” in *Journal of Health Politics, Policy and Law* (Vol. 34, No. 4), p. 524.

³⁴ Robinson, Ray (1999). “Perspectives on cost sharing” in *Eurohealth* (Vol. 5, No. 3), p. 24.

³⁵ Canadian Health Services Research Foundation (2001). “Mythbusters: User fees would stop waste and ensure better use of the healthcare system” in *Eurohealth* (Vol. 11, No. 1), p. 29.

costs. In regards to the pricing of pharmaceuticals, it would be reasonable to assume that if payers are able to employ either of these measures effectively then there would be more scope in negotiations given that more “popular” treatments could generate more revenue, thus bringing pricing more in line with market conditions.

Payers may also be able to temper demand for treatments by imposing waits, which aim to subtly impede immediate access so as not to overload certain services. The gatekeeper system, common in the United Kingdom and Scandinavia, is designed to control costs and unnecessary interventions by authorising health professionals, usually GPs, to control access by necessitating referrals. In theory, prescription medicines also do this, as they prevent medicines being accessed without approval from a relevant health professional. Whilst this is mainly designed for safety, to prevent patients accessing treatments that are not appropriate for their condition based on bad information, it is the case that payers sometimes use prescribing rules for GPs to favour some medicines over others, or to encourage medicines not to be prescribed at all.³⁶ The effect of this type of prioritising on pharmaceutical prices is unclear, although payers that are able to influence the prescribing practices of GPs towards cheaper treatments are likely to be those that employ more aggressive cost-containment strategies designed to bring pharmaceutical prices down. Such strategies are also easier for public payers, who generally employ the professionals that they are attempting to influence.

In general, however, most payers choose to prioritise treatments by assessing the supply and establishing what represents value for money and refusing to reimburse those that do not. This process is called health technology assessment (HTA), where treatments and services are appraised based on their relative effectiveness, commonly expressed in price per quality-adjusted life year (QALY)³⁷, in comparison with other treatments. HTA has now become routine in most Western healthcare systems and some payers even impose implicit thresholds, above which treatments are summarily refused reimbursement. Such mechanisms appear flawed as they fail to even consider the possibility that a medicine could bring extraordinary benefits, thus justifying an extraordinary outlay. In truth, thresholds tend to represent politically determined cut-off points.³⁸ Prioritising pharmaceuticals through HTA has a significant impact on how they are priced, as manufacturers will be acutely aware that they need their products to be reimbursement. This is no more obvious than in public payer systems, in which a decision not reimburse a pharmaceutical effectively inhibits market entry. Yet, whilst public payers may have greater scope and

³⁶ For more information on incentives and standards established for GP prescribing in Europe and North America, see Stockholm Network (2010). *Patient safety and comfort: the challenges of switching medicines*.

³⁷ 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.

³⁸ Stockholm Network (2008). *What Price for a Year of Life? The Threshold Discussion in Health Technology Assessment*, p. 4.

ability to prioritise pharmaceuticals, it is often patients in public payer systems that seem to resent most the obstruction to effective treatments and services. Often this is because of the lack of recourse for patients who are denied the treatment, although relief can sometimes be provided through risk-sharing and top-up payments.

Securing innovation

Future healthcare needs are likely to become more pressing and it is highly unlikely that such challenges will be adequately overcome without accelerated levels of medical innovation. The total number of new medicines developed and introduced in the United States and the EU fell from 155 between 1987 and 1991 to 127 between 2000 and 2004, thus emphasising the importance of increasing innovation in the future.³⁹ Such innovation will not be achieved however without long-term investment into R&D that can be targeted towards discovering and understanding unmet needs and diseases. Hopes that such significant drug developments could be performed primarily by the State instead of the private sector have continuously been disappointed. Instead, competitive research by the private sector has shown itself to be a key driver for innovators to make the enormous investments needed – and to shoulder the risks associated – in order to achieve improvements and breakthroughs.⁴⁰ As a result, most payers have a significant interest in ensuring that future medical innovations are achieved, whilst having moderate involvement in achieving such breakthroughs.

All payers are naturally keen to embrace generic medicines because of their low costs. Yet, without the R&D investments of the original innovator, such savings cannot be made and such medicines will not be able to reach patients. As a result, payers need to balance their desire to slash budget costs in the short-term with their need for continued investment in medical innovation. Such trade-offs between static and dynamic efficiency are vital in achieving a situation where the best possible price today can be agreed without harming other policy objectives that are also important to the national economy.⁴¹ In theory, this should apply to both public and private payers as they have both invested in the healthcare system and so will be affected by future challenges. Yet public payers tend to be more affected by current economic conditions because their budgets are drawn from tax receipts, which make them more susceptible to political considerations. Furthermore, public payers that have sub national decision-makers, which remain financed by national governments, can sometimes escalate costs and generate what is called “moral

³⁹ Golec, Joseph, and Vernon, John (2010). “Financial Effects of Pharmaceutical Price Regulation on R&D Spending by EU versus US Firms” in *Pharmacoeconomics 2010* (Vol. 28, No. 8), p. 623.

⁴⁰ Pfister (2009), p. 9.

⁴¹ Docteur, Elizabeth (2008). “Pharmaceutical pricing policy in a global market” PowerPoint presentation at Workshop on Current Pharmaceuticals Challenges European Health Forum Gastein (01/10/08).

hazard", where spending decisions are made insulated from risk.⁴² As a result, it is sometimes suggested that fragmented private payers make more stable financing decisions and can commit more readily to long-term planning. However, it should also probably be noted that public systems often have access to other tools such as taxation and patent legislation which can, depending on the tool and how it is wielded, either aid or hinder future innovation,.

The regulation of any industry is important, yet it would be impractical if these were to impede innovators substantially because this could both hamper access to medicine in the short term and impact upon the discovery of new medicines in the long term. Certainly, some smaller healthcare markets can try to demand underpriced pharmaceuticals, and indeed many do, because they do not suffer if their domestic industry's products are underpriced, or because their domestic economies benefit more from other types of industries. Yet, none of the major healthcare markets are in this situation. They will need to look to create an environment for pharmaceutical innovation which is as conducive as possible.

⁴² Glied (2009), p. 598.

The Pricing Spectrum

With the relationship between payers and pricing identified, the paper will now delve deeper into price regulation itself. In doing so, it will endeavour to showcase those regulations that are most common and how they affect the pharmaceutical prices established. In regulating prices, all payers are in theory attempting to fix upon the fair price for a pharmaceutical, which considers both their needs and the demands of manufacturers. Yet in truth, faith that some sort of perfect price can be agreed is unrealistic, particularly given the current healthcare environment.

As a result, a pricing spectrum has emerged that balances between two distinct points. On one side are prices established within a controlled pricing environment by payers, whilst on the other end of the spectrum are those prices established within a market-based pricing environments by manufacturers. While very few systems can be accurately described as absolutely controlled or absolutely market-based, most systems can be located somewhere on the spectrum. In addition, whilst it might be more encouraging believing that all prices established represent a fair price, in truth such decisions are subjective and likely to represent either the controlled price or the market-based price. The concepts of both the controlled price and the market-based price are explored in more detail below.

The controlled price

The justification for the intervention of payers into the pharmaceutical market is frequently seen as a response to imperfections that can cause market failure. Pharmaceuticals are considered to be a merit good and intervention is justified on the basis of safety, quality, and efficacy, as well as to ensure equity in access.⁴³ However, whilst market failure in pharmaceuticals may be serious enough to warrant intervention, it is not always the case that price controls may constitute part of this intervention.⁴⁴

There are a number of stages at which prices of pharmaceuticals can be regulated. This paper will mainly focus on regulations at the manufacturer level, sometimes referred to as the list price, which is the original price of the pharmaceutical and does not include any discount or incentives offered by manufacturers. In addition to this, control can also be exerted to amend the wholesale price, which is the price charged by wholesalers to retailers that will include wholesale mark-ups, and also the pharmacy retail price, which is

⁴³ *Ibid.*

⁴⁴ World Health Organisation (1998).

the price charged by pharmacists to the general public that will include pharmacy mark-ups, dispensing fees and VAT.⁴⁵ Sometimes a combination of price regulations at all these levels can occur.

A number of different mechanisms will now be laid out and, whilst this list is by no means exhaustive, it does provide a good overview of schemes that are currently in practice. Most of them are designed to control pharmaceutical prices on the supply side, for example, through price negotiations, profit controls and cross-country comparisons. In doing so, payers are ultimately establishing a controlled price, which reflects the value of a pharmaceutical as well as the need to contain costs. Internal referencing is also discussed. However, this is a price control on the demand side, which attempts to reduce the number of patients accessing a particular medicine and, in theory, could allow manufacturers to set a market-based price (though in practice it forces a controlled price onto them).

Price negotiations

By intervening in the establishment of prices for pharmaceuticals, payers are making it clear that they feel it is necessary to use mechanisms to create a controlled price, so as to meet cost-containment objectives. The most common way of creating a controlled price is through direct negotiations between payer and manufacturer that allow payers to exert their monopsony, in order to bring down prices. Sometimes the prices agreed will also reflect a “cost-plus” calculation, allowing for research, production and marketing costs and an allowance for profit per product.⁴⁶

To assist payers in this process, pharmaco-economic evaluations similar to HTA may be used which attempt to analyse pharmaceuticals in comparison to other treatments, whilst calculating value on the basis of the benefit to society and beyond. In France, pricing negotiations between manufacturers and the Pricing Committee (CEPS) are conducted after an assessment by the Transparency Committee of a pharmaceutical's medical benefit and innovativeness. These evaluations ultimately define pharmaceuticals by a so-called ASMR rating (Amelioration du Service Medical Rendu or “improvement in actual benefit”), with a rating of ASMR 1 indicating significant therapeutic value and ASMR 5 showing no therapeutic improvement of benefit as compared to existing products. Once evaluated, these ratings have a significant effect on how products are priced and manufacturers of ASMR 1 and 2 products are even permitted to suggest a price themselves which, if not rejected by the CEPS, will be accepted within a fortnight.⁴⁷ Pharmaco-economic evaluations may also compel payers not to enter negotiations altogether. In

⁴⁵ European Commission (2006). *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, PXLII-XLIII.

⁴⁶ World Health Organisation (1998).

⁴⁷ European Commission (2006), p. 229.

Germany, where pharmaceuticals are evaluated by the Institute for Quality and Efficiency in Health Care (IQWiG) on behalf of the Federal Joint Committee (G-BA), if a pharmaceutical is evaluated as “innovative”, defined as a patent-protected pharmaceutical with a significant therapeutic advantage, it will be allowed to be priced freely.⁴⁸

Even with the assistance of pharmaco-economic evaluations, it can still be very difficult to establish what an appropriate controlled price should be. Calculations will often rely on extensive and reliable information from manufacturers themselves, which can be difficult to both obtain and interpret.⁴⁹ As a result, the price that is usually agreed upon for one product will need to be considered within the context of all agreements between the payer and that particular manufacturer. Some controlled prices may be set low but are accepted by the manufacturer because the controlled price of another product is set high. In addition, other arrangements, such as price volume agreements and rebates, can form part of the settlement in direct negotiations. The difficulty with negotiations which set prices for pharmaceuticals is that the controlled price agreed often proves to be static, offering very little incentive to manufacturers to increase efficiency or save costs once the price is set.⁵⁰ In addition, pharmaco-economic evaluations at launch will inevitably only be able to assess value on the basis of clinical data, without the advantage of considering benefits in the “real world”.

To counter this in some way, a relatively new concept in regards to pharmaceutical pricing is to base the controlled price purely on an assessment of “value”, which many perceive could allow for a more dynamic perspective. This value-based pricing, to be introduced in the United Kingdom from 2014, is seen as a useful way of obtaining value for money whilst refocusing innovation towards unmet needs. In the United Kingdom, it will work by determining a range of maximum thresholds that would be set to reflect the values that different medicines offer. Such “values” would be assessed and the benefits of medicines would be compared with the benefits that could be gained if the funds required were used to help patients elsewhere. These maximum thresholds would be adjusted to take into account the “burden of illness” and “therapeutic innovation and improvement”.⁵¹ It is argued that by pricing in this way, payers are able to encourage manufacturers to focus their R&D towards those unmet needs that would warrant higher thresholds.

⁴⁸ *Ibid.*

⁴⁹ Rietveld, Ad, and Haaijer-Ruskamp, Flora (2002). “Policy Options for Cost Containment of Pharmaceuticals” in *International Journal of Risk & Safety in Medicine* (Vol. 15), p. 31.

⁵⁰ *Ibid.*

⁵¹ Stockholm Network (2011), p. 9.

However, it is problematic to accurately and universally define value, with many payers often focused too much on delivering welfare gains at the lowest possible market price and producer gains in terms of the fair market return achieved on sales.⁵² As a result, there are concerns that value-based pricing could in fact be used as a veiled attempt to cut costs on the basis of an inaccurate definition of value, which would result in a reduction of pharmaceutical revenues. This could strangle drug development, and thus would not be dynamic.⁵³ In addition, it is also unrealistic to assume that individual changes in domestic pricing will be able to refocus the R&D strategies of global pharmaceutical manufacturers as a whole. Furthermore, the belief that politicians should be charged with accurately directing investments belies the fact that it is industry which is best placed to anticipate the potential benefits, compare this to their own costs and decide whether it is right to invest.⁵⁴

Controlling profits

In some ways, controlling only the overall profits of pharmaceutical manufacturers can technically permit products to be priced freely, although constraints on profits inevitably limits the prices that manufactures are able to set.⁵⁵ Through profit controls, a certain return on capital (ROC) ceiling is established for individual companies, above which they are not allowed to receive further payment. To be effective, any ceiling - whether it is on price or profit - will need to be below a level deemed to be monopolistic.⁵⁶ However, as with pricing, determining the threshold for what is constituted unreasonable is especially difficult and will often be decided by direct negotiations between the payer and the manufacturer.

The most relevant example of profit control regulations is in the United Kingdom, where the Pharmaceutical Price Regulation System (PPRS) has existed since 1957. This scheme restricts maximum profits for manufacturers of branded pharmaceuticals that have annual sales to the NHS of more than £1 million.⁵⁷ Currently, the PPRS sets a common ROC target of 21%, with marketing expenses and information expenses restricted to 4% of turnover and R&D allowances of up to 28%.⁵⁸ In addition, an upper and lower “margin of tolerance” is in place that allows manufacturers to retain additional profits strictly based on innovation and which permits price rises if profits fall below a certain level. The profit frameworks that are decided upon in the United Kingdom are established by regular negotiations between the Department of Health and the main industry body, the Association of the British

⁵² McGuire, Alistair et al (2008). “Pricing pharmaceuticals: Value based pricing in what sense?” in *Eurohealth* (Vol. 14, No. 2), p. 3.

⁵³ Atkin, Gavin (2010). “The new weapon in medicines pricing” in *Chemist + Druggist* (22/05/10), p. 22.

⁵⁴ Claxton, Karl et al (2011). *Value-based pricing for pharmaceuticals: Its role, specification and prospects in a newly devolved NHS*, p. 15.

⁵⁵ Bloom et al (1996), p. 33.

⁵⁶ Kelton, Christina, and Rebelein, Robert (2007). “A General Equilibrium Analysis of Public Policy for Pharmaceutical Prices”, in *Journal of Public Economic Theory* (Vol. 9, No. 2), p. 297.

⁵⁷ Department of Health website - Introduction to pharmaceutical price regulation. See <http://tinyurl.com/67goo9l> (Accessed on 14 Mar. 11).

⁵⁸ European Commission (2006), p. 756.

Pharmaceutical Industry (ABPI). Whilst the negotiations may sometimes be seen as combatants engaging in a round of jousting, the discourse can sometimes be constructive, allowing for a fair amount of give and take.⁵⁹ In the last couple of PPRS negotiations, voluntary across-the-board price cuts – 3.9% in 2009 and 1.9% in 2010 - and the wider use of patient access schemes (also known as risk sharing schemes) have been agreed.⁶⁰ It also seems to have offered more flexibility than some other static mechanisms where price adjustments cannot be made in response to changing market conditions.⁶¹

However, it should probably be noted that the United Kingdom government is now looking to scrap profit control regulations on the basis that it believes they put the NHS “in the position of either having to pay high prices that are not always justified by the benefits of a new drug, or having to restrict access”.⁶² Such claims, though, are at odds with the fact that pharmaceutical prices in the United Kingdom are generally lower than in most developed healthcare markets and that limited patient access may have more to do with the relatively rigorous, and time-consuming, HTA conducted by the highly-developed National Institute for Health and Clinical Excellence (NICE) to decide the NHS’ benefits package.

Cross-country comparisons (external referencing)

The use of international comparison tools, whereby the controlled price is set on the basis of a “basket” of prices for the same product in other countries, is particularly common in Europe. Yet France is the only one of the G5 major healthcare nations to employ it.⁶³ In France, cross-country comparisons are used as part of the CEPS’ negotiations with manufacturers and, in doing so, the CEPS often ensures that the controlled price does not exceed the average price in the EU.⁶⁴ These cross-country comparisons attempt to lessen price differentiation by encouraging price transparency, although by doing so they can hinder access to medicine in low-income countries.⁶⁵ This is because manufacturers may be incentivised to delay or halt the launch of some medicines in lower-priced markets to avoid the risk of spill-over into other markets.⁶⁶

The OECD has argued that cross-country comparisons do not lead to cost-effective pricing, as it believes that prices should depend on health needs, income, preferences and healthcare costs, which vary across

⁵⁹ Warner, Norman (2011). *A Suitable Case for Treatment*, p. 189.

⁶⁰ Stockholm Network (2011), pp. 7-9.

⁶¹ Rietveld and Haaijer-Ruskamp (2002), p. 32.

⁶² UK Department of Health (2010), p. 9.

⁶³ G5 = France, Germany, Japan, United Kingdom and the United States.

⁶⁴ European Commission (2006), p. 229.

⁶⁵ Docteur (2008).

⁶⁶ *Ibid.*

countries.⁶⁷ Furthermore, it suggests that by reducing the ability of manufacturers to price to market, cross-country comparisons contribute to a convergence of prices, which is likely to result in price inflation. Cross-country comparisons also create a complicated web of interlinked pharmaceutical prices that compel price changes in one market to affect the price of pharmaceuticals in many other markets. The table below gives an indication of this complexity by showing OECD countries that compare their pharmaceutical prices with Canada, the United States and the EU5. Blue boxes indicate that they are in that country's "basket" and thus these markets are sensitive to external price changes.

Cross-country comparison countries and their benchmarks (blue)⁶⁸

	Canada	France	Germany	Italy	Spain	UK	USA
Australia						x	
Austria		x	x	x	x	x	
Belgium		x	x				
Canada	x	x	x	x		x	x
Finland		x	x	x	x	x	
France			x	x	x	x	
Greece		x	x	x	x	x	
Hungary			x	x	x		
Iceland		x	x	x	x	x	
Ireland		x	x			x	
Japan		x	x			x	x
Luxembourg		x	x				
Mexico	Six countries with the highest sales						
Netherlands		x	x			x	
New Zealand	x						
Norway			x			x	
Portugal		x		x	x		
Slovakia		x	x	x			
Spain		x	x	x		x	
Sweden				x			
Switzerland		x	x	x		x	
Turkey		x			x		

Source: Kyle (2007)

France, Germany and the United Kingdom are the three most commonly referenced by OECD countries, therefore deductions in prices in these countries will be likely to reduce prices across a range of other lesser markets and may be resisted by manufacturers, because of this global effect.⁶⁹

⁶⁷ *Ibid.*

⁶⁸ Keyhani, Salomeh (2010). "US Pharmaceutical Innovation in an International Context" in *American Journal of Public Health* (Vol. 100, No. 6), p. 1077.

⁶⁹ Richter, Anke (2008). "Assessing the Impact of Global Price Interdependencies" in *Pharmacoeconomics* (Vol. 26, No. 8), p. 655.

Internal referencing

Internal referencing operates on the basis of establishing a maximum reimbursement ceiling for products, or classes of products, irrespective of price variations that may exist on the market.⁷⁰ In doing so, many pharmaceuticals are grouped so that they can be compared with other products with identical bioactive ingredients (phase 1), related products with different indications (phase 2) or with pharmaceuticals that treat the same condition (phase 3).⁷¹ Such groupings are controversial because whilst some may be willing to accept the interchangeability of pharmaceuticals that have identical active ingredients, (i.e. branded medicines with their generic equivalents) there is strong opposition, often from patients themselves, to the idea that one pharmaceutical can be alternated with another because it treats the same condition. These so-called “jumbo” groups have been used in Germany for many years.⁷² In addition, the mechanism for calculating the reference price also varies in most systems, with some determining the price by calculating the average price of all products in groups and others establishing the cheapest priced product, or generic, as the reference price.⁷³

In most systems, referencing acts as an indirect form of cost sharing, as it sets reimbursement prices above which patients are expected to pay any difference between the reference price and the product they wish to consume.⁷⁴ The objective essentially has been to limit the rise in pharmaceutical expenditure by containing the prices that payers must fully reimburse.⁷⁵ Internal referencing originated in Europe and - significantly - is used by both France and Germany, although it is now also practised by many other countries worldwide.⁷⁶ Internal referencing is not strictly a price control mechanism, as manufacturers are usually free to set any price for their product. However, the fact that ceilings are established, above which products are likely to lose their market share if they are avoided by prescribers, suggests that a manufacturers' freedom to set prices is significantly hampered.⁷⁷

Referencing is a mainly pro-generic policy, as generics are almost certainly likely to be the lowest product within off-patent reference groups because of the low costs of production. Understandably, payers in Europe and North America have embraced generic medicines because of their perceived cost advantages in relation to the branded leader.⁷⁸ Fundamentally, this is the purpose of introducing referencing, i.e. to

⁷⁰ Kanavos (2008), p. 3.

⁷¹ Ioannides-Demos, Lisa (2002). “Reference-Based Pricing Schemes” in *Pharmacoeconomics* (Vol. 20, No. 9), p. 579.

⁷² *Ibid.*

⁷³ Mrzcek (2002), p. 459.

⁷⁴ Jamiai, Nadia, Thomson, Sarah, and Mossialos, Elias (2004). “An overview of cost sharing for health services in the European Union” in *Euro Observer* (Vol. 6, No. 3), p. 2.

⁷⁵ Mrzcek (2002), p. 459.

⁷⁶ Podnar, Klement et al (2007). “How Reference Pricing for Pharmaceuticals Can Increase Generic Share of Market: The Slovenian Experience” in *American Marketing Association* (Vol. 26, No. 1), p. 90.

⁷⁷ Ioannides-Demos (2002), p. 580.

⁷⁸ Kanavos, Panos (2008b). “Generic policies: Rhetoric vs. reality” in *Euro Observer* (Vol. 10, No. 2), p. 1.

increase the use of cheap generics rather than continuing to pay for more expensive branded pharmaceuticals. However, whilst this may be the aim, referencing often fails to deliver this in practice. The table below compares generic prices in France and Germany (which both have referencing) with the United Kingdom (which does not). It shows that, three years after generic entry, generic pharmaceuticals themselves were priced much lower, as a percentage of the branded price, in the United Kingdom than in both France and Germany. This would support the argument that, as well as bringing branded prices down, referencing also encourages generic manufacturers to increase their prices towards the reference price, rewarding generics with higher prices than they would have under competitive market conditions. Prices for generics tend to cluster around the reference price, and decline more slowly over time than in countries where generics operate in a more competitive environment.⁷⁹ Furthermore, the average generic penetration up to three years after first entry is higher in the United Kingdom than in both France and Germany, suggesting that much lower priced generics in the United Kingdom are creating an incentive for further prescribing in the long-term. Studies have also suggested that although the prices of pharmaceuticals covered by referencing tend to decrease, leading to a reduction in cost to payers, there are no long-term savings because medicines that were not part of the reference price scheme often have their prices increased at levels greater than the price decreases.⁸⁰

Pricing and penetration of generics in three selected European countries, 2008⁸¹

	Average difference between branded price and generic price up to 3 years after first entry (%)	Average generic penetration up to 3 years after first entry (%) (potential maximum generic market share, by sales)
France	30-40%	10-20% (30%)
Germany	25-40%	45% (85%)
United Kingdom	80%	55% (95%)

Source: Kanavos, Panos (2008b)

Yet generic manufacturers have the advantage of pricing medicines low, because they do not have the financial burden of researching and developing pharmaceuticals, whilst they also choose only those products with proven commercial success, thus offering little contribution to the process of innovation.⁸² The OECD suggests that referencing can reward innovation by allowing manufacturers to obtain price premiums from patients that choose to pay extra for their product, although it also acknowledges that this is counteracted by the fact that patients do not have the relative cost-effectiveness information to

⁷⁹ Hanisch, Melinda and Kanavos, Panos (2008). "Cost containment: impact and consequences" in *Eurohealth* (Vol. 14, No. 2), p. 1.

⁸⁰ *Ibid.*

⁸¹ *Ibid.*

⁸² Ager, Brian (2009). "European Commission's inquiry into the pharmaceuticals sector" in *The Lancet* (Vol. 374), p. 1819.

make such decisions.⁸³ By definition, referencing brings down the rewards for innovative medicines to the benefit, it seems, of bringing up the price of non-innovative medicines. It cannot therefore be seen to effectively reward innovation.⁸⁴

Other concerns about internal referencing include a fear that it creates a two-tier healthcare system with unemployed and low-income earners forced to receive drugs at or below the reference price, as they are less likely to pay the extra co-payment. This may hinder patients' access to possibly more effective medicines, as the most effective products may be subject to an unaffordable co-payment. Although this factor will vary greatly depending on the medicines that are being alternated and, as many new products will be excluded if there is no clear substitute, internal referencing should not in theory obstruct patient access to medicines too far.⁸⁵ It also represents an encroachment on physicians' freedom to prescribe and may discourage individualisation of drug therapy, whilst placing more demand on doctors' time since they are often required to obtain an authority to prescribe non-reference products.⁸⁶ Finally, internal referencing is also criticised for introducing an unwanted or undesirable financial component to the physician-patient relationship.⁸⁷

The market-based price

Product prices are a means of regulating access to goods in a free market and allow goods to be allocated in response to private desires. Whilst pharmaceuticals are goods that benefit society, they also carry significant private benefit and this, along with the ability of people to pay, gives rise to a demand for pharmaceuticals that is sufficient to incentivise a market to be created.⁸⁸ Market-based pricing allows pharmaceutical prices to more accurately reflect fluctuating market conditions. While manufacturers are still required to oblige with all the relevant safety, efficacy and quality requirements - which ensures that their products are not dangerous, ineffective or substandard - when it comes to pricing they are able to establish the market-based price for their product. Payers would generally agree to reimburse whatever price manufacturers set, but will still be wary of the need to prioritise services. However, even in the freest of scenarios (most of which are unlikely in health policy) manufacturers will always remain subject to competition policy, which aims to prevent collusion, price fixing and economic dominance.

⁸³ Docteur (2008).

⁸⁴ Cueni (2008), p. 9.

⁸⁵ Mrazek (2002), p. 460.

⁸⁶ Ioannides-Demos (2002), p. 587.

⁸⁷ Puig-Junoy, Jaume (2010). "Impact of European Pharmaceutical Price Regulation on Generic Price Competition" in *Pharmacoeconomics* (Vol. 28, No. 8), p. 661.

⁸⁸ World Health Organisation (1998). *Pharmaceuticals and Health Sector Reform in the Americas: An Economic Perspective*, section. See <http://apps.who.int/medicinedocs/en/d/Jh2926e/7.2.html#Jh2926e.7.2> (Accessed on 12 Jul. 11).

Presently, the major healthcare system that comes closest to pricing pharmaceuticals in this way is the United States. However, it is not the case that pharmaceutical prices in the United States are completely unregulated. Manufacturers are still susceptible to intense political pressure, and scrutiny, and they are generally unable to set high prices without needing to justify them.⁸⁹ In addition, and more importantly, manufacturers in a market-based pricing environment are still compelled to establish efficient prices because their products are more exposed to competition whether from generics when off-patent or even when on-patent from therapeutic counterparts.⁹⁰ In fact, over the past 20 years the United States has had an average of three drugs competing on the market per therapeutic class.⁹¹

Adam Smith once wrote that the real price of everything is “the toil and trouble of acquiring it” and in establishing the market-based price for their products pharmaceutical manufacturers need to take many factors into account.⁹² Since the 1990s, pharmaceutical manufacturers have developed a fairly mechanistic approach to pricing, conducting expensive pricing research studies to determine the perfect price point.⁹³ Some of the costs that manufacturers incur will now be briefly identified and, in doing so, it is suggested that such costs will naturally factor into the market-based price established for pharmaceuticals. However, it is important to consider from the outset that, even when establishing the market-based price, few manufacturers are likely to value pharmaceuticals on the basis of a pure cost calculation and that most market-based prices are likely to reflect the amount that can be reasonably extracted from the market. Yet costs are nevertheless important as they provide the basis for the market-based price, upon which a changeable return on investment is likely to be added.

Chief among the factors to take into account is the very lengthy process of drug development, which has substantial costs in investment years before any potential returns can be earned.⁹⁴ The most recent industry estimates suggest that it costs \$1.3 billion for a pharmaceutical manufacturer to develop a product that reaches the market, in total taking between 10 and 15 years.⁹⁵ An overview of this development process is shown below.

⁸⁹ Golec and Vernon (2010), p. 616.

⁹⁰ Mrazek (2002), p. 453.

⁹¹ Kyle, Margaret (2007), p. 88.

⁹² Adam Smith (1976), *An Inquiry into the Nature and Causes of the Wealth of Nations*, (Edited by Campbell, Skinner and Todd), Liberty Fund, p. 49.

⁹³ Kolassa, E.M. (1997), *Elements of Pharmaceutical Pricing*, The Haworth Press, Binghamton., p. 2.

⁹⁴ DiMasi, Joseph and Grabowski, Henry (2007), “The Cost of Biopharmaceutical R&D: Is Biotech Different” in *Managerial and Decision Economics* (Vol 28), pp. 469-479.

⁹⁵ Pharmaceutical Research and Manufacturers of America (PhRMA) (2010), *Profile: Pharmaceutical Industry*, inside front cover.

Research and Development of a Pharmaceutical⁹⁶

Discovery research				Development research						Regulatory review		Post-marketing development
				Phase I		Phase II		Phase III				
1	2	3	4	5	6	7	8	9	10	11	12	<i>Years</i>

Source: ABPI (2011)

One key reason for the high costs of development is the experimental nature of the pharmaceutical discovery research stage, which can make it incredibly difficult for companies to identify the potential for initial innovations from the outset. Very many discoveries will fail to reach the final phase of development and so have to be abandoned. In fact, on average only 1 out of 5,000 molecules that are developed by pharmaceutical manufacturers ever reach the market.⁹⁷

Added to this comes the challenge of the small window that manufacturers have to take advantage of exclusive rights to the intellectual property for the product's active pharmaceutical ingredient. This is because manufacturers of pharmaceutical products only ever receive a twenty-year period from the time they file a patent for its unique element. This will take place right at the beginning of the drug development process and must be filed in all markets where the product is to be marketed. This exclusivity is designed to incentivise innovators to continue to invest in R&D needs and so is awarded on the basis that facilitating higher prices can create incentives for R&D.⁹⁸ Once the patent expires, manufacturers must then compete with generic copies of their medicine created through a relatively inexpensive process of reverse-engineering. These copies need only to prove their equivalence to the original pharmaceutical and are not required to prove safety and efficacy through clinical trials. As a result, generic manufacturers are able to price products at a much lower cost, on average 25% less than the original brand name medicines, proportionate to the lower manufacturing expenses incurred in bringing their medicine to the market.⁹⁹

Consequently, the market-based price of an approved and marketable product will often need to take into consideration not just its own R&D costs, but also those of the other 4,999 molecules developed

⁹⁶ Association of the British Pharmaceutical Industry (ABPI) (2011). *Did You Know? Facts and figure about the pharmaceutical in the UK*, p. 10.

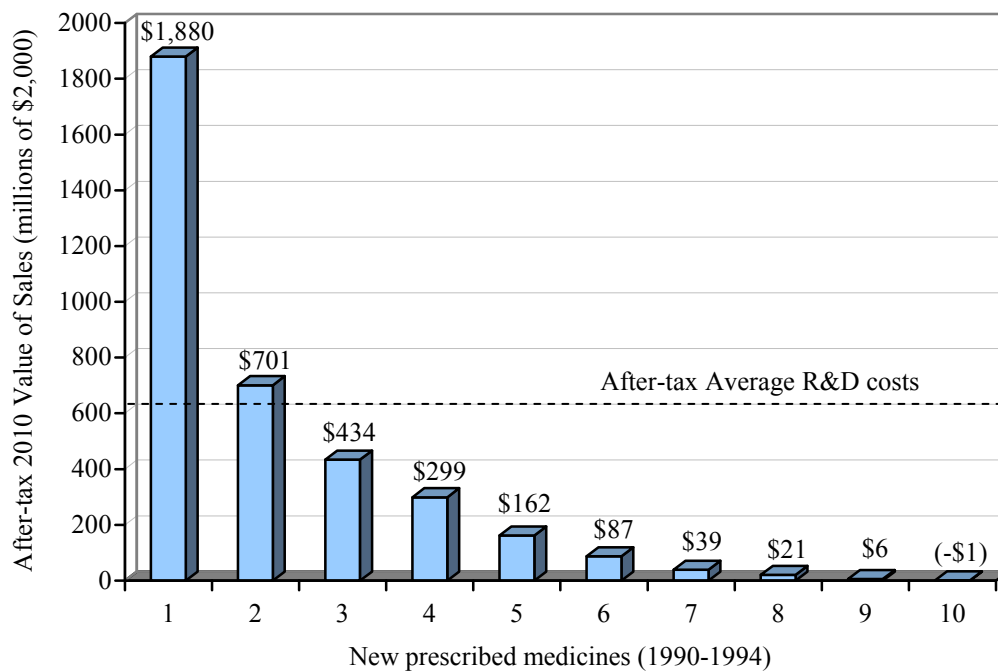
⁹⁷ PhRMA (2010).

⁹⁸ Ridley (2005), p. 652.

⁹⁹ Canadian Health Services Research Foundation (2008). "Mythbusters: Generic drugs are lower quality and less safe than brand name drugs" in *Eurohealth* (Vol. 14, No. 4), p. 33.

without success, within a limited period of exclusivity. Yet, very few medicines actually do this. The graph below shows the after-tax value of sales (in 2009) for new prescription medicines introduced in the United States between 1990 and 1994 and compares this to the after-tax average R&D costs spent on them. It shows that only two of these ten approved medicines between 1990 and 1994 had actually recouped their R&D costs by the time they dropped off patent.

Sales Value of New Prescription Medicines, between 1990 and 1994¹⁰⁰



Source: PhRMA (2010)

United States – getting more for more?

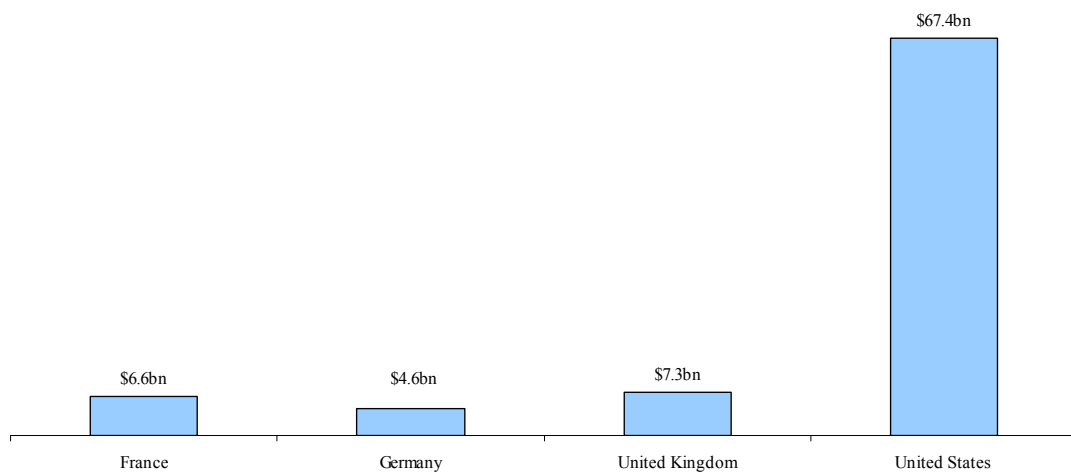
One fundamental validation of market-based pricing is its ability to encourage medical innovation, by expanding the incentive for manufacturers to invest in R&D. In the United States, the market for pharmaceuticals is far more profitable than any other market and this success can justifiably be put down to the absence of price regulations.¹⁰¹ Between 1998 and 2004, United States manufacturers generated 76% of their sales from within their own market, whilst even a majority of the sales of European manufacturers were generated from the American market. As a consequence, more flourishing

¹⁰⁰ *Ibid.*

¹⁰¹ Golec and Vernon (2010), p. 616.

manufacturers in the United States are able to contribute more liberally to R&D investments towards discovering future medicines. The graph below highlights this by detailing the investment in R&D within the United States and compares this to its closest markets in Europe and North America – the gap is substantial, even when accounting for different population sizes.

Current annual spending by pharmaceutical industry on R&D (in \$ billions)



Source: LEEM¹⁰², BfI,¹⁰³ ABPI¹⁰⁴ and PhRMA¹⁰⁵

The consequence of a flourishing pharmaceutical market for American patients is significant, as it improves innovation and encourages better access to effective medicines. In fact, as the graph below suggests, the availability of new medicines in the United States is better than in any other healthcare system. It shows the access to 69 new global pharmaceuticals (post-1996) and the mean time lags (in months) of these medicines reaching the market. It discovers that patients in the United States have greater access to new and effective medicines, whilst the time taken to bring these to the market is shorter than in other markets. Many studies argue that this is because price regulations delay the decision to launch pharmaceuticals in controlled markets. Counterproductively, this can prove significantly costly for healthcare systems, as the cost of untreated conditions may be substantial and because limited market entry reduces competition, which could help bring down prices.¹⁰⁶

¹⁰² Les Entreprises du Médicament website – France, the pharmaceutical industry and biotechnology. See <http://tinyurl.com/65b8sgy> (Accessed on 31 May 2011).

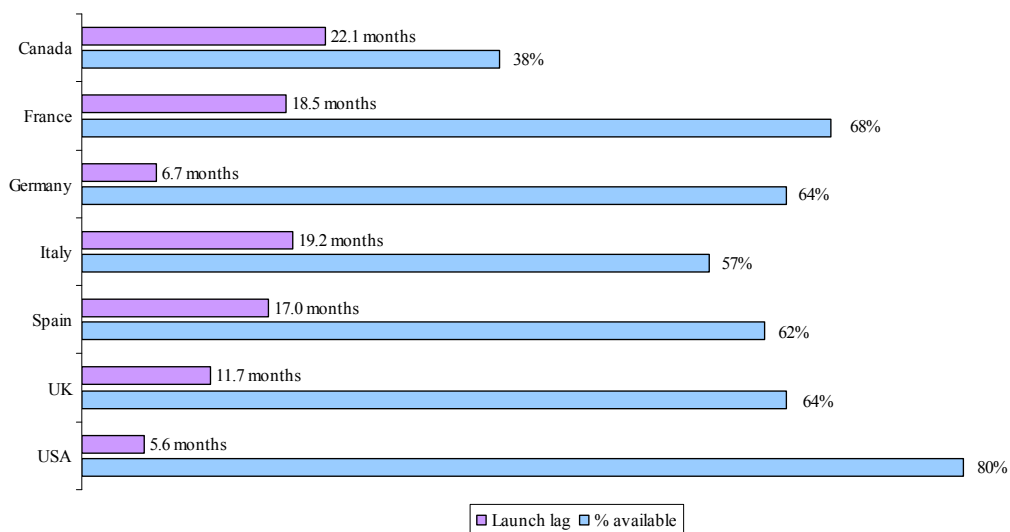
¹⁰³ Bundesverband der Pharmazeutischen Industrie e.V. (2010). *Pharma-Data*

¹⁰⁴ ABPI (2011), p. 11.

¹⁰⁵ PhRMA (2011), inside front cover and p. 42.

¹⁰⁶ Kyle (2007), pp. 88-89.

Availability (blue) and launch lag (purple) of new medicines (post-1996), 2005¹⁰⁷



Source: Danzon (2008)

Some studies have even attempted to calculate the value that market-based pricing brings to the United States, by comparing the growth of R&D investments with that of the more controlled environment of the EU. Between 1986 and 2004, R&D growth in the EU was 5.4%, yet it is estimated that without price regulations this would have been 6.6%. On this basis, it can be claimed that countries in the EU have lost \$4.96bn in R&D spending, failed to discover 46 new medicines and sacrificed 31,925 R&D jobs years as a result of price regulations.¹⁰⁸ Furthermore, had the United States introduced price regulations between 1986 and 2004, it would have also seen a suppression in R&D investment growth, resulting in \$12.67bn foregone in R&D spending, a loss of 117 new medicines and cost 81,550 job years.¹⁰⁹ Moreover, other studies have argued that the future introduction of price regulations in the United States could reduce the life expectancy of American people (aged between 55 and 59 years old) by two-tenths (0.8%), as well as reducing the life expectancy of Europeans (aged between 55 and 59 years old) by one-tenth (0.7%).¹¹⁰ In the long-term this would become more pronounced, with American price regulations estimated to reduce the life expectancy of Americans and Europeans (aged between 55 and 59 in 2060) by 0.7 years, which would represent around 2.8 percent.¹¹¹

However, whilst the above highlights significant benefits of market-based pricing in respect to innovation and patient access, such an approach is not without its drawbacks, and in particular it is commonly held

¹⁰⁷ Danzon, Patricia (2008). "Cross-National Effects of Pharmaceutical Pricing Policies" PowerPoint presentation (29/10/08).
¹⁰⁸ Golec and Vernon (2010), p. 625.
¹⁰⁹ *Ibid.*
¹¹⁰ Lakdawalla, Darius et al (2008). "U.S. Pharmaceutical Policy In A Global Marketplace" in *Health Affairs* (16 December 2008), p. 143.
¹¹¹ *Ibid.*

that market-based pricing produces higher pharmaceutical prices. This is perhaps unsurprising given that most price regulations are designed to bring prices down and the cause is likely to rest with the calculation of the market-based price. As identified above, the market-based price in a market will not always be strictly based on a cost calculation and will need to also consider a reasonable return on investment. This financial return, or indeed profit, makes the whole process worthwhile and thus incentivises the manufacturer to attempt to achieve future innovations. Unfortunately, in any market it is very difficult to assess what return is reasonable and sometimes the market-based price can reflect the objective of maximising profits, which will drive up prices for some products that attract greater demand.¹¹²

The amount that American prices are higher by is a matter of debate, with the widespread impression often exaggerating the comparative prices of pharmaceuticals.¹¹³ The conclusions of studies into the price of pharmaceuticals in the United States can vary wildly, with some showing American prices anywhere between 6% and 33% higher than European ones, and others showing that the prices of innovative drugs in Australia, for example, are similar to those paid under United States programmes.¹¹⁴ This is because not all of these studies use consistent methodologies. However, a reliable study has recently been performed by Kanavos and Vondoros (2011). This new study shows that ex-factory prices in the United States were more than double those of the EU5 (France, Germany, Italy, Spain and the UK), yet differences between public prices were not as dramatic. This distinction between ex-factory and public prices is significant since factors such as VAT and distribution costs can add to the price of pharmaceuticals. Payers are only likely to be concerned with public prices as this will reflect the amount that they will pay, and so a 19% VAT rate for pharmaceuticals in Germany compared to 0% in the United States and the United Kingdom, for example, will need to be considered as part of the price.¹¹⁵

Kanavos and Vondoros also show that price differences between the United States and the EU5 were wider for off-patent markets than for on-patent markets, which is not surprising considering that most price regulations in Europe are designed to bring branded medicine prices in line with their generics, (although because of greater generic competition, the United States was in fact shown to have lower generic prices).¹¹⁶ All in all, the Kanavos and Vondoros study illustrates that public prices in the United

¹¹² World Health Organisation (1998),

¹¹³ Kanavos and Vondoros (2011), p. 15.

¹¹⁴ *Ibid.*

¹¹⁵ European Commission (2011). VAT Rates Applied in the Member States of the European Union, p. 4.

¹¹⁶ *Ibid.*

States were on average 29% higher than the main European healthcare markets, when controlling for age, generic presence, exchange rates and therapeutics.¹¹⁷

Europe – getting more for less?

What market-based pricing shows in theory, and the United States market shows in practice, is that an absence of price regulations can cultivate growth in R&D spending, thus facilitating greater discovery and uptake of innovative medicines, but that this may cause higher pharmaceutical prices.¹¹⁸ Payers and policymakers are therefore forced to decide if they are willing to tolerate this in order to benefit from enhanced innovation. Whilst most payers will be keen for these added benefits, often R&D growth rates are easily overlooked and sacrificed, as they are unlikely to generate as much political attention as large budget deficits. Yet pharmaceutical pricing involves a trade-off between the costs of pharmaceuticals in the short-term for current generations and the need for future innovations to benefit future generations.¹¹⁹

As pharmaceuticals are of value across the globe, the present situation is problematic. Firstly, it puts the United States in a position where the introduction of price regulations could have a significant effect not just on its domestic market but also on other markets abroad.¹²⁰ Moreover, many other healthcare systems are effectively “free-riding” on patients in the United States and thus not paying their fair share towards the current cost of drug development and future innovation.¹²¹ The graph below highlights this by showing the top eight global sources for pharmaceutical innovation, both in terms of the location of inventors and also in terms of where new products are first patented.¹²² It shows how the United States is currently doing much of the heavy lifting for the rest of the world and the gap in innovation between America and the rest of the world.

¹¹⁷ *Ibid.*

¹¹⁸ Sood, Neeraj et al (2008). “The Effect Of Regulation On Pharmaceutical Revenues: Experience in Nineteen Countries” in *Health Affairs* (December 2008), p. 126.

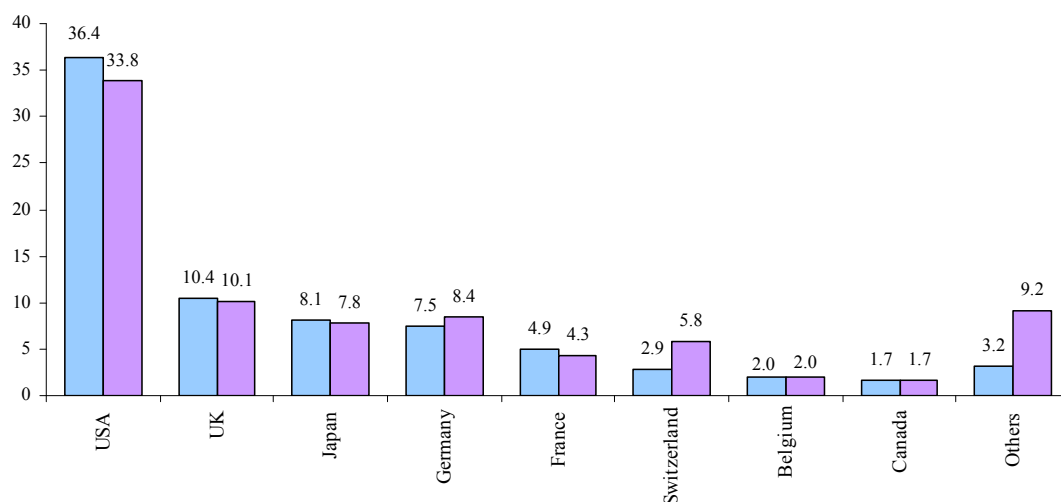
¹¹⁹ Lakdawalla et al (2008), p. 138.

¹²⁰ *Ibid.*

¹²¹ Keyhani (2010), p. 1075.

¹²² *Ibid.*

**Global source of pharmaceutical innovation classified by location of the company headquarters
(blue) and patent assignees (purple), 1992-2004¹²³**



Source: Keyhani (2010)

The table below brings together the United States and the EU5 and shows the number of pharmaceuticals launched in those countries and their origins, in respects to the location of their headquarters. It highlights the dependency of these markets on the United States as the primary source of pharmaceuticals launched in their markets, beyond even those produced domestically.¹²⁴ The United State Congress has put this down to price controls, which it says do not adequately recognise or “reward innovation” and place an unfair burden on American consumers.¹²⁵ Medicines are an R&D-intensive good that provide benefits to consumers globally, whilst pharmaceutical policies have global impacts and a further appreciation of these externalities needs to be taken into account in national policy making.¹²⁶ It seems inequitable to allow American patients to pay more for their medicines in order to secure innovation in the future that everyone benefits from. Certainly market-based pricing may seem expensive when looking towards the US market, yet this cost burden would naturally be reduced if shared among major healthcare systems.

¹²³ *Ibid.*

¹²⁴ Kyle (2007), p. 89.

¹²⁵ Roughead, Elizabeth et al (2007). “Prices for Innovative Pharmaceutical Products That Provide Health Gain: A Comparison Between Australia and the United States” in *Value in Health* (Vol. 10, No. 6), p. 514.

¹²⁶ Danzon (2008). See also, Docteur (2008).

Cross-tabulation of drugs by origin and country of launch¹²⁷

		Origin country					
		France	Germany	Italy	Spain	UK	USA
Launch market	France	133	56	18	1	57	216
	Germany	97	108	18	2	76	259
	Italy	92	67	96	3	75	185
	Spain	79	59	35	36	66	182
	UK	73	45	10	1	97	237
	USA	56	38	7	-	70	307

Source: Kyle (2007)

¹²⁷ Keyhani (2010), p. 1077.

Conclusions

This paper shows the expansive nature of pharmaceutical price regulations and the pricing spectrum that has emerged as a result. In theory, as pharmaceuticals will never be left completely to the market, policymakers will always have a role in regulating how patients access their medicines. But there is, however, no neat solution to the conflicting demands of both payers and manufacturers and so a more nuanced approach is necessary.

A number of conclusions can now be made that sum up the key findings of this paper. The first is an acknowledgement that the future presents policymakers with the challenge of an ageing population: less people working and available to pay for health services via taxation and more people reliant on using them. Thus, many healthcare systems, as they currently stand, will struggle to remain financially sustainable in the future unless they are willing to undergo funding or other reforms. Payers have a duty to control healthcare budgets to prevent them from becoming a strain upon the overall economy, yet current attempts to reduce health spending often focus disproportionately on pharmaceutical spending.

As a result, heterogeneous pharmaceutical price regulations have established price differentiations across different markets that do not reflect relative market sensitivities, rather a government's willingness to pay for pharmaceuticals or more accurately their desire to get a "good deal". Public payers appear better placed to negotiate these lower prices to providers using their monopsony and concentrated revenue streams, however they can also create more limited patient choice and access, which will have negative consequences for patients. Yet all payers, whether public or private, have a keen interest in ensuring that the environment within which innovators exist is conducive as possible to the innovation process.

In implementing price regulations, a number of different tools can be identified that allow the payer to control the price of pharmaceuticals:

- (i) Direct price negotiations are the most common, but they can often appear static and the price agreed upon is unlikely to reflect a pharmaceutical's true value, even when evaluated by pharmaco-economic assessments;
- (ii) Profit controls in the United Kingdom allow the controlled price to be established in a different, and possibly more flexible, way although it may hinder innovation as a result,;
- (iii) Cross-country price comparisons (so called internal referencing) have created a complex web of controlled prices that has the potential to hinder patient access to innovative

medicines, whilst creating an exterritorial dimension to pharmaceutical prices that can diminish the influence of domestic policymakers;

- (iv) Internal referencing greatly influences pharmaceutical prices and can lead to an environment where innovative medicines are priced lower than usual, to the benefit of non-innovative medicines that are priced higher than usual.
- (v) Finally, the experience of market-based pricing in the United States suggests that a lack of control over prices can encourage more flourishing markets that generate higher R&D investments by manufacturers. This in turn fosters higher levels of innovation, although usually at the expense of higher pharmaceutical prices for payers. As a consequence, medical innovation, which is vital for overcoming future challenges, seems to have been drawn towards the American market to the benefit of all markets.

Policy Recommendations

The above conclusions are useful for understanding the theory of pharmaceutical price regulations and their practice in developed healthcare systems but this paper also goes on to provide constructive suggestions to policymakers as to how best to continue in the future. Specifically, it offers the following three policy recommendations inferred from its findings.

1. Build sustainable healthcare systems on the basis of patient choice as a fundamental right

Many suggestions are currently being offered to policymakers for how best to deal with the impending challenges that could significantly impede the future provision of healthcare in Europe and North America. The most constructive contribution that this paper can make is to recommend that healthcare reforms aim to empower patients above all else, so that they can choose to allocate resources in the most effective way. A patient's right to choose how their healthcare contributions are spent is not just a democratic entitlement; it is also an efficient decision-making tool that will ultimately reward those treatments and services that are the most effective. This is as important in regards to pharmaceutical pricing as anywhere else and whilst the tendency among some payers may be towards the unconditional prohibition of certain treatments, such decisions must be made with alternative recourse available to prevent patients from losing their right to patient choice. In economies, where every possible good and service can be acquired and personalised within seconds, it is amazing that a vital commodity such as healthcare is still often managed in a protracted, one-size-fits-all way. There is still the possibility of providing a social safety net without necessarily meaning that the state has to provide all the services or make healthcare decisions on behalf of patients.

2. Pricing is not a race to the bottom

This paper has not set out to suggest that payers are wrong to control pharmaceutical prices, indeed it has expressed throughout that payers have a duty to taxpayers to manage their budgets in an effective manner. However, it does recommend that all payers take care when contemplating price controls and also that payers (especially the State) consider them as part of an overall approach, which understands the efficiency of healthcare systems in a dynamic way. Short-term measures to reduce pharmaceutical prices artificially are firstly unlikely to deal with rising healthcare budgets and are also likely to hamper innovation further down the road. Wide differentiation between pharmaceutical prices in relatively similar

markets is indicative of a race to the bottom where prices are not reached on the basis of “real world” market conditions. The European Union is a good example of this malfunction and Member States need to address this issue by encouraging price controls to be implemented on the basis of the long-term sustainability of healthcare systems. In doing this, it will no doubt become apparent that price regulations should not simply be used as mechanisms for extracting the lowest possible price for a product, but as tools for assessing a more accurate value of medicines to society.

3. Innovation comes at a price

A key theme throughout this paper has been the focus on innovation, which is achieved through secured investment in research and development, mainly funded by manufacturers themselves. Yet, this should not convince policymakers that they are powerless in securing the next generation of breakthrough medicines. Indeed, they have direct influence over the total investments made into research and development, and thus the intensity of innovation that can be achieved. Enhanced innovation is however costly and the bearers of this cost will be manufacturers, who in turn will pass on the price to payers. Currently, it seems that Europe is getting “more for less” in this respect and could be accused of “free-riding” on the willingness of Americans to pay more for their pharmaceuticals. Rather than allowing American payers, and their patients, to shoulder this burden alone it seems right that other developed countries should step up to the plate and attempt to encourage greater investment in their own markets. Doing so would not only make the supply of global innovation more diverse and thus more sustainable, but would also no doubt benefit each country’s economy and healthcare system. This is not to say that this can only be achieved through market-based pricing, but that countries should employ all the tools that they have at their disposal to focus their domestic industries towards greater investment in innovation.

Bibliography

This paper aims to offer an original perspective on pharmaceutical pricing, although it relies heavily throughout on a number of studies and sources, identified below:

Publications

- Atkin, Gavin (2010). "The new weapon in medicines pricing" in *Chemist + Druggist* (22/05/10).
- Ager, Brian (2009). "European Commission's inquiry into the pharmaceuticals sector" in *The Lancet* (Vol. 374).
- Bloom, Karen et al (1996). "Lessons from international experience in controlling pharmaceutical expenditure III: regulating industry" in *British Medical Journal* (Vol. 313).
- Canadian Health Services Research Foundation (2001). "Mythbusters: User fees would stop waste and ensure better use of the healthcare system" in *Eurohealth* (Vol. 11, No. 1).
- Canadian Health Services Research Foundation (2008). "Mythbusters: Generic drugs are lower quality and less safe than brand name drugs" in *Eurohealth* (Vol. 14, No. 4).
- Claxton, Karl et al (2011). *Value-based pricing for pharmaceuticals: Its role, specification and prospects in a newly devolved NHS*. Centre for Health Economics, University of York.
- Cueni, Thomas (2008). "Can Europe afford Innovation" in *Eurohealth* (Vol. 14, No. 2).
- Danzon, Patricia (2008). "Cross-National Effects of Pharmaceutical Pricing Policies" PowerPoint presentation (29/10/08): The Wharton School, University of Pennsylvania.
- DiMasi, Joseph and Grabowski, Henry (2007). "The Cost of Biopharmaceutical R&D: Is Biotech Different" in *Managerial and Decision Economics* (Vol. 28).
- Docteur, Elizabeth (2008). "Pharmaceutical pricing policy in a global market" PowerPoint presentation at Workshop on Current Pharmaceuticals Challenges European Health Forum Gastein (01/10/08).
- Gerlinger, Thomas (2010). "Health Care Reform in Germany" in *German Policy Studies* (Vol. 6, No. 1).
- Glied, Sheny (2009). "Single Payer as a Financing Mechanism" in *Journal of Health Politics, Policy and Law* (Vol. 34, No. 4).
- Harvard Kennedy School (2007). *Health Care Delivery Covered Lives – Summary of Findings*: Mossavar-Rahmani Center for Business and Government, Harvard University
- Hancher, Leigh (2008). "An expanding toolkit for the European pharmaceutical market" in *Euro Observer* (Vol. 10, No. 3).
- Hanisch, Melinda and Kanavos, Panos (2008). "Cost containment: impact and consequences" in *Eurohealth* (Vol. 14, No. 2).
- Hutchings, Adam (2010). "Rewarding innovation? An assessment of the factors that affect price and reimbursement status in Europe" in *Journal of Medical Marketing* (Vol. 10, No. 1).
- Ioannides-Demos, Lisa (2002). "Reference-Based Pricing Schemes" in *Pharmacoeconomics* (Vol. 20, No. 9).
- Jamali, Nadia, Thomson, Sarah, and Mossialos, Elias (2004). "An overview of cost sharing for health services in the European Union" in *Euro Observer* (Vol. 6, No. 3).
- Kanavos, Panos (2000). "The WTO-TRIPS Agreement: Areas of dispute and implications" in *Eurohealth* (Vol. 6, No. 4).
- Kanavos, Panos, and Kowal, Stacey (2008a). "Does pharmaceutical parallel trade serve the objectives of cost control" in *Eurohealth* (Vol. 14, No. 2).
- Kanavos, Panos (2008b). "Generic policies: Rhetoric vs. reality" in *Euro Observer* (Vol. 10, No. 2).
- Kanavos, Panos, and Vondoros, Sotiris (2011). "Drug US: are prices too high?" in *The Royal Statistical Society* (March 2011).
- Kelton, Christina, and Rebelein, Robert (2007). "A General Equilibrium Analysis of Public Policy for Pharmaceutical Prices" in *Journal of Public Economic Theory* (Vol. 9, No. 2).
- Keyhani, Salomeh (2010). "US Pharmaceutical Innovation in an International Context" in *American Journal of Public Health* (Vol. 100, No. 6).
- Kolassa, E.M. (1997). *Elements of Pharmaceutical Pricing*. The Haworth Press, Binghamton.
- Kyle, Margaret (2007). "Pharmaceutical Price Controls and Entry Strategies" in *The Review of Economics and Statistics*, (Vol. 89, No. 1).
- Lakdawalla, Darius et al (2008). "U.S. Pharmaceutical Policy In A Global Marketplace" in *Health Affairs* (16 December 2008).
- Malcomson, James (2004). "Health service gatekeepers" in *RAND Journal of Economics* (Vol. 35, No. 2).
- McGuire, Alistair et al (2008). "Pricing pharmaceuticals: Value based pricing in what sense?" in *Eurohealth* (Vol. 14, No. 2).
- Mrazek, Monique (2002). "Comparative Approaches to Pharmaceutical Price Regulation in the European Union" in *Croatian Medical Journal* (Vol. 43, No. 4).
- Oliver, Adam (2009). "The Single-Payer Option: A Reconsideration" in *Journal of Health Politics, Policy and Law* (Vol. 34, No. 4).
- Pfister, Lukas (2009). "Drug development: a complex and risky but potentially rewarding collaborative process" in *Eurohealth* (Vol. 15, No. 4).
- Podnar, Klement et al (2007). "How Reference Pricing for Pharmaceuticals Can Increase Generic Share of Market: The Slovenian Experience" in *American Marketing Association* (Vol. 26, No. 1).
- Puig-Junoy, Jaume (2010). "Impact of European Pharmaceutical Price Regulation on Generic Price Competition" in *Pharmacoeconomics* (Vol. 28, No. 8).
- Richter, Anke (2008). "Assessing the Impact of Global Price Interdependencies" in *Pharmacoeconomics* (Vol. 26, No. 8).

- Ridley, David (2005). "Price Differentiation and Transparency in the Global Pharmaceutical Marketplace" in *Pharmacoeconomics* (Vol. 23, No. 7).
- Rietveld, Ad, and Haaijer-Ruskamp, Flora (2002). "Policy Options for Cost Containment of Pharmaceuticals" in *International Journal of Risk & Safety in Medicine* (Vol. 15).
- Robinson, Ray (1999). "Perspectives on cost sharing" in *Eurohealth* (Vol. 5 No. 3).
- Roughead, Elizabeth et al (2007). "Prices for Innovative Pharmaceutical Products That Provide Health Gain: A Comparison Between Australia and the United States" in *Value in Health* (Vol. 10, No. 6).
- Smith, Adam (1976). *An Inquiry into the Nature and Causes of the Wealth of Nations* (edited by Campbell, Skinner and Todd), Liberty Fund, Indianapolis.
- Stockholm Network (2008). *What Price for a Year of Life? The Threshold Discussion in Health Technology Assessment*, Stockholm Network, London.
- Stockholm Network (2010). *Patient safety and comfort: the challenges of switching medicines*, Stockholm Network, London.
- Stockholm Network (2011). *A New Value-Based Approach to the Pricing of Branded Medicines*, Stockholm Network, London.
- Sood, Neeraj et al (2008). "The Effect Of Regulation On Pharmaceutical Revenues: Experience in Nineteen Countries" in *Health Affairs* (December 2008).
- Warner, Norman (2011). *A Suitable Case for Treatment*, Grosvenor House, Surrey.

Official sources

Association of the British Pharmaceutical Industry
 Bundesverband der Pharmazeutischen Industrie
 European Commission
 German Bundestag
 Les Entreprises du Médicament
 Organisation for Economic Cooperation and Development (OECD)
 Pharmaceutical Research and Manufacturers of America (PhRMA)
 United States White House
 United Kingdom Department of Health
 United States Census Bureau
 World Health Organisation