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Options for Efficient Regulation of the UK Pharmaceutical Market

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"Opciones para una regulación eficiente del mercado farmacéutico del Reino Unido"

Resumen

La industria farmacéutica se encuentra regulada económicamente en casi todos los países del mundo. En el Reino Unido, esta industria se encuentra regulada bajo el plan de regulación de precios farmacéuticos (PPRS) para todas aquellas ventas de medicamentos de marca al Servicio Nacional de Salud (NHS) desde 1978. En el pasado, el PPRS se componía de una combinación de regulación de precios y de márgenes de beneficio. Sin embargo, desde 2014 el PPRS tiene por primera vez como principal mecanismo regulador un límite a la tasa de crecimiento de los ingresos agregados para los medicamentos de marca vendidos al NHS. Este último cambio fue una nueva medida para limitar la creciente carga presupuestaria que generan los costos de adquisición de medicamentos y generó cuestionamientos sobre la forma actual en que se regula la industria. En línea con esta última medida, en este documento revisamos otras opciones para la futura regulación de la industria farmacéutica en el Reino Unido, estableciendo opciones que merecen valer la pena considerar. Con este propósito, resumimos la regulación farmacéutica en otros cinco países de la OCDE, identificando opciones que pueden ser relevantes para el Reino Unido. Luego, analizamos otras experiencias de regulación económica en el sector de servicios públicos del Reino Unido, identificando opciones que pueden aplicarse a la industria farmacéutica del Reino Unido. Finalmente, discutimos las opciones para el futuro de la industria farmacéutica del Reino Unido y los problemas que deben abordarse. Consideramos que cada una de estas opciones tienen el potencial de reducir la duplicación de instrumentos regulatorios y la carga de la regulación general.

Palabras clave: industria farmacéutica, regulación económica, precios de medicamentos, Reino Unido.

"Options for Efficient Regulation of the UK Pharmaceutical Market"

Abstract

The pharmaceutical industry is subject to economic regulation by governments almost all over the globe. In the UK, the pharmaceutical industry has been subject to the Pharmaceutical Price Regulation Scheme (PPRS) to sell branded medicines to the National Health Service (NHS) since 1978. The PPRS has, in the past, comprised of a combination of price and profit control. However, since 2014, the PPRS has, for the first time as the main regulatory mechanism, an aggregate revenue growth rate cap for branded medicines sold to the NHS. This last change was a new measure to limit the increasing burden of the medicines procurement costs, and it triggered questioning about the current way the industry is regulated. In line with this, in this paper, we review other options for the pharmaceutical industry's future regulation in the UK, setting out options that seem to be worth considering. With this purpose, we summarise pharmaceutical regulation in five other OECD countries, identifying options that may be relevant to the UK. Then, we review the UK utility sector's experience of economic regulation identifying options that may apply to the UK pharmaceutical industry. Finally, we discuss options for the future of the UK pharmaceutical industry and issues to be addressed. We consider each option the potential for reducing any duplication of regulatory instruments and a general reduction in the burden of regulation.

Keywords: pharmaceutical industry, economic regulation, United Kingdom, pharmaceutical prices.

Códigos JEL: I11, I18, L11, L51

Options for Efficient Regulation of the UK Pharmaceutical Market

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Master's Thesis

Abstract

The pharmaceutical industry is subject to economic regulation by governments almost all over the globe. In the UK, the pharmaceutical industry has been subject to the Pharmaceutical Price Regulation Scheme (PPRS) to sell branded medicines to the National Health Service (NHS) since 1978. The PPRS has, in the past, comprised of a combination of price and profit control. However, since 2014, the PPRS has, for the first time as the main regulatory mechanism, an aggregate revenue growth rate cap for branded medicines sold to the NHS. This last change was a new measure to limit the increasing burden of the medicines procurement costs, and it triggered questioning about the current way the industry is regulated. In line with this, in this paper, we review other options for the pharmaceutical industry's future regulation in the UK, setting out options that seem to be worth considering. With this purpose, we summarise pharmaceutical regulation in five other OECD countries, identifying options that may be relevant to the UK. Then, we review the UK utility sector's experience of economic regulation identifying options that may apply to the UK pharmaceutical industry. Finally, we discuss options for the future of the UK pharmaceutical industry and issues to be addressed. We consider each option the potential for reducing any duplication of regulatory instruments and a general reduction in the burden of regulation.

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1 Introduction

This study aims to offer an insight into the so-called Pharmaceutical Price Regulation Scheme (PPRS) in the UK. The PPRS is the main mechanism for regulating the prices of prescribed drugs covered by the National Health Service (NHS). The study of drug price regulation in the UK is fascinating for several reasons. First, unlike other industries in the country, it does not rely on a free-market system: the pharmaceutical prices have strict government-level price control. Second, the pharmaceutical industry is one of the few UK high-technology industries manufacturing high value-added products, which has succeeded in competing in the international market. Finally, the price regulation regime in place in the UK is complex and unique in the world, and their significant differences with other current regimes in developed countries place questions about potential changes and improvements that could be made.

The purpose of this paper is two-fold. First, to review the pharmaceutical industry's current economic regulation in the UK, summarize the pharmaceutical regulations in the other five OECD countries, and identified options that may be relevant to the UK. We also reviewed the experience of economic regulation in the UK public utility sector and determined the options that might apply to the UK pharmaceutical industry. Second, in the light of this review, to consider options for the future regulation of the pharmaceutical industry in the UK and setting out options that seem to be worth considering. To this aim, we considered reducing the duplication of regulatory measures and the potential to generally reduce the regulatory burden. It should be noted that the main focus of this paper is on the branded, patented segment. The off-patent segment's current regulatory arrangements are set out, but reform proposals for this segment are outside the scope.

The structure of this article is as follows. Section 2 sets out the economic rationale for governments to regulate the pharmaceutical industry, which is different from that for most other regulated sectors and provides an overview of the UK environment. Section 3 summarises regulation in five other OECD countries, identifying options relevant to the UK. We review the experience of economic regulation of the UK utility sector in Section 4, identifying options that may be relevant to the UK pharmaceutical industry, including a section on the process of negotiation. Finally, in Section 5, we review and analyze alternative options for future regulation in the UK pharmaceutical sector and address issues.

2 The rationale for pharmaceutical price regulation

The pharmaceutical industry is subject to economic regulation by governments, concerned that prices may be too high and competition too low. In many countries governments (or other third party payers) pay for medicines, and hence they are concerned about the impact on government finances of medicines expenditure.

The reasons for regulating are, however, quite distinct from other sectors. Most regulated industries are in the utility sector, such as gas, water, airports, electricity and telecommunications. All of them share a common characteristic: they all exhibit significant market power problems, often as a result of the natural monopoly characteristics of some parts of the infrastructure they use to supply their customers.

The pharmaceutical industry is not an intrinsic natural monopoly. The knowledge generated by the R&D is easily appropriated by others, and marginal costs of production, relative to R&D costs, are usually relatively low. It would be possible for another firm to enter the market at a lower average cost if it could free ride on the incumbent's R&D costs.

In order to avoid free-riding on R&D costs and enable innovator firms to recoup their R&D investments, government-granted patents are needed to protect intellectual property by creating a temporary monopoly with the purpose of creating incentives for innovation: innovator firms are able to set prices above the marginal cost of production to recoup the sunk cost they incurred during the R&D phase. As long as innovation is protected, prices are higher than the marginal costs of supply and the quantities are lower, which raises issues about the appropriate levels of prices and profits. Static efficiency is reduced (prices are above the marginal cost of production) to enhance dynamic efficiency (recouping of the fixed costs of R&D to incentivize future innovation).[1]

Patents protect against the entry of generic copies for the life of the patent, but do not prevent the entry of therapeutic competitors. R&D is thus a competitive process and several firms, using new knowledge about disease mechanisms and potential "targets" for new drugs, could develop in parallel, different drugs for the same therapeutic use. The high rate of entry into pharmaceutical-biotechnology industry research indicates that R&D is structurally competitive. Thus, neither patents nor natural monopoly provide a rationale for regulating pharmaceutical prices (Danzon, 2006).[2]

[1] R&D costs are a sunk, global joint cost, and thus it is necessarily to have a set of prices internationally such that companies can recoup these.

[2] Another important difference between utilities and pharmaceutical companies costs concerns the timing of sunk expenditures. Historically, utilities incurred relatively little capital cost prior to regulatory approval of a new facility. By comparison, pharmaceutical firms must incur almost all of

The rationale for drug price regulation derives from the role of insurance or third party payment in the market for medicines. The health care market in most countries has classic principal-agent problems: the government or public or private insurers (the principals) would like doctors (the agents) to prescribe in a cost-effective manner evaluating the budgetary cost versus the therapeutic benefit. The therapeutic benefit goes to the patients (consumers) who generally do not choose or pay for the medicines they consume. Doctors (who are agents for the patient as well as for the insurer) decide on the appropriated treatment the patient takes, and the government (or the social or private insurer in many countries) is the one that pays for health care services. Even though the cost of health care is passed on to individuals by paying taxes, or social or private health insurance premiums, most patients and doctors are insensitive to pricing at the point of prescribing a treatment and focus on the relative health and related benefits. This creates an environment in which suppliers can charge higher prices than they would without insurance. This can lead to excessive expenditure in the absence of some form of price regulation. Patient co-payments are a weak antidote if insurance is to retain its value as providing protection to patients from financial problems (Bloom and Van Reenen, 1998).

The case for economic regulation is therefore because of structural challenges on the demand side rather than on the supply side. There is a debate to be had as to whether a competitive health insurance market can overcome this demand side challenge. In many high income country health care systems, however, including the UK, the government is the payer. This has three consequences. First, the government is both regulator and procurer. The regulatory bargain is also a procurement bargain. Second, the government has strong monopsony purchasing power and could overcompensate for the principal-agent insurance problem, driving prices down below those that could be regarded as providing a reasonable return on R&D[3]. However, pressure from patients for access to treatments could be regarded as an offsetting political effect reducing government bargaining power. Finally, the government has economic objectives as well as health objectives. Economic regulatory agreements in pharmaceuticals can cover elements of industrial/science strategy as well as price and procurement arrangements.

their sunk costs prior to applying for regulatory approval. This difference in the timing has implications for risk. Also, the fixed/sunk costs are generally associated with R&D expenditures,which by their very nature have an uncertain effect on revenue (Fellows and Hollis, 2013).

[3] As we have noted, R&D recovery is on a global basis. Efficiency requires value-based differential pricing on a global basis. A government can always argue that it is for others to make a greater contribution.

3 Pharmaceutical Regulation in the UK

In the UK, the pharmaceutical industry has been subject to the Pharmaceutical Price Regulation Scheme (PPRS) for sales of branded medicines to the National Health Service (NHS) since 1978.[4] The aim of the (latest) PPRS is to limit the overall expenditure of the NHS on medicines covered by the scheme, while promoting a strong industry by providing an appropriate business investment environment to recover costs and make reasonable profits. The current PPRS has a number of important principles and objectives as a result of the commitment between the Government and the ABPI to strengthening the UK environment for life sciences. These principles are presented by the Department of Health (DH, 2013) (our added bold typeface):

1. **Provide stability and predictability to the Government and the Industry**, by enabling certainty of planning and by helping the NHS and the industry develop sustainable financial and investment strategies;
2. **Support the NHS by ensuring that the branded medicines bill stays within affordable limits**, and deliver value for money for the NHS by securing the provision of safe and effective medicines at reasonable prices, and **encouraging the efficient development and competitive supply of medicines**;
3. **Improve access to innovative medicines commensurate with the outcomes they offer patients** by ensuring that medicines approved by NICE are available widely in the NHS, encouraging the NHS to promote the rapid adoption and diffusion of innovative medicines and treatments recommended by NICE commensurate to the outcomes they offer patients;
4. **Reduce bureaucracy and duplication**, and avoid unforeseen burdens on either party over the coming years; and
5. **Support the Government's growth and innovation agenda for life sciences**, by promoting a strong and profitable pharmaceutical industry that is both capable of and willing to invest in sustained research and development to encourage the future availability of new and improved medicines for the benefit of patients and the industry in this and other countries.

Considering the current PPRS objectives and thinking about objectives for the

[4]The scheme also applies to branded generics, vaccines, in vivo diagnostics, blood products, dialysis fluids, branded products supplied through tendering processes and on central or local contracts, biotechnology products, and biosimilars. Earlier forms of the PPRS have existed since the 1950s.

next PPRS with the principles of efficient regulation, goals one might want from a regulatory agreement are:

1. A stable regime for an agreed (five year) period;
2. Avoiding overregulation, both in terms of (i) the bureaucracy involved in regulating the market and (ii) avoiding duplication, i.e. companies are subject to conflicting policy instruments that are intended to achieve the same outcome.
3. Reasonable *levels* of prices and also efficient *relative* prices, i.e. the price of drug A relative to drug B reflects their relative effectiveness. The latter requires some price flexibility as knowledge changes over the lifetime of a product. The use of a cost-effectiveness threshold (i.e. price paid for a QALY) by NICE means that agreement on pricing requires agreement on the cost-effectiveness threshold;
4. Providing reassurance to the government about the affordability of medicines expenditure over the agreement period;
5. Delivering outcomes for patients, which requires use of value-for-money medicines;
6. Using competition where possible to bring value for money, innovation to patients, and a reduced need for regulation;
7. Achieves incentives for future innovation;
8. Achieves benefits for "UK plc" , i.e. promotes the UK life sciences base.

As it was previously pointed out, the main focus of this article is on brand patents, this is the reason why we focus on the PPRS and not in the regimes that regulate generic medicines (voluntary Schemes W and M).

3.1 What is the PPRS for?

The PPRS is a non-contractual voluntary scheme between the Department of Health (DH), on behalf of the Government of the UK and Northern Ireland, and the Association of the British Pharmaceutical Industry (the ABPI), on behalf of the pharmaceutical industry in the UK. Companies in the scheme account for about 80% of branded medicines supplied to the NHS. The current PPRS is a five-year scheme, entered into force on 1 January 2014 and due to expire on 31 December 2018.

The PPRS has in the past comprised of a combination of price and profit control. Whilst companies had freedom of pricing at launch, they were not allowed to increase price subsequently and historically, every time the PPRS had been re-negotiated (every five years or so), there had been across the board, one-off or phased, price cuts. However, the current, 2014, PPRS, has for the first time as the main regulatory mechanism an aggregate revenue growth rate cap for branded medicines sold to the

NHS. It does this by requiring pharmaceutical companies to make payments 'back' to the DH if growth in NHS spend on branded medicines supplied by PPRS members exceeds the agreed percentage (the 'allowed growth rate') in each year of the PPRS. Sales of new products are excluded from the sales on which the payment back is calculated, i.e. these sales are in the total but excluded from the eligible revenue over which the rebate percentage is calculated.

The PPRS price and profit restraints remain. Under the PPRS prices of new drugs can be freely set, but firms are prevented from raising prices of existing drugs without the Department of Health (DH) permission. The profit control places a limit on the profits that individual companies can earn from supplying medicines to the NHS, while allowing a return within certain limits.

The allowed target of return is six per cent Return on Sales (ROS) or 21 per cent Return on Capital (ROC) a year.[5] There is also a 50 per cent margin of tolerance.[6] If a firm's return is above the higher tolerance band, it must cut drug prices or refund the surplus to the DH. If its rate of return falls below the lower tolerance band, then the firm can apply for price increase. In determining profits, there are R&D, marketing and information allowances.

As noted, the 2014 PPRS changed the cross-portfolio one-off list price reduction every five years to a new system involving a cross-industry cap on sales growth. In practical terms, this involves quarterly cash rebates paid to the DH by each scheme member. The rebate percentage is calculated according to the excess expenditure, and some other adjustments, and will be the same across all companies in the PPRS. This percentage is re-calculated every year. Members of the PPRS with sales of less than £5m in the previous calendar year are not required to make PPRS Payments to the Department.[7]

The effects of the change in the way the PPRS works it is not easy to measure. In particular, it is not easy to disentangle the effects of the new PPRS on the industry from other two factors. One factor might be that the 2014 PPRS seems to have improved the uptake of new medicines: the median rate of uptake in the UK between 2011 and 2015 was higher than the median rate of uptake between 2007

[5] Sales rather than capital will be used to determine the profit target for scheme members whose Annual Financial Return (AFR) home sales exceed their average assessed home capital employed by a factor of 3.5 or more. Most PPRS member companies will be in this position, i.e. ROS rather than ROC companies.

[6] It was 40% in the PPRS 2009.

[7] In the previous PPRS, companies with sales of more than £5m were required to make payments only on the excess of sales over those £5m (if sales were £6m, payments were made only over £1m, the excess over £5m). Under the 2014 PPRS, companies with sales of more than £5m now pay over the total sales value (if sales are £6m, payments are now made on the basis of £6m). Arguably, this is harmful to small firms as it introduces a high marginal "tax" rate on growing beyond £5m .

and 2012. Nevertheless, it still remains below relative to the international average in the first three years after launch (HM Government, 2015; 2017). It is also clear that the prospect of repayments to the DH for medicines expenditure exceeding the agreed total did not impact local budget holder behaviour as their budgets remained fixed in advance – albeit higher because of the DH's expectation of a payback. The second factor is that it is less clear how much stability the agreement has brought. PPRS net growth has been in line with the requirement because of the rebates. However, companies have faced uncertainty about the size of the rebate and the DH has pre-committed funds to the NHS based on its own assumptions about growth rates. This latter point required an agreement in December 2016 for a fixed rebate for 2017 and a "cap and collar" put on the rebate for 2018.[8]

3.2 The PPRS and the Value-Based Pricing

In 2007, the Office of Fair Trading published a PPRS market study. It did not like the ROC/ROS scheme, as it was concerned about the transfer pricing component and the challenge of ensuring an appropriate allocation of global costs. It recommended that "*Government reform the PPRS, replacing current profit and price controls with a value-based approach to pricing*" (Office of Fair Trading, 2007). The concept of value-based pricing (VBP) was to integrate health technology assessment (HTA) with price setting. The Government recognised the importance that value is reflected in the PPRS. Two important reforms were subsequently set out.

First, from 2009, the DH and The Association of the British Pharmaceutical Industry (ABPI)[9] agreed to set out two new pricing flexibility measures in the PPRS that were aimed at linking more closely the value of medicines to what the NHS paid for them through a pragmatic and systematised approach in the PPRS. The two mechanisms are Flexible Pricing (FP) and Patient Access Schemes (PASs). The new government elected in 2010 made a commitment to move to a value-based pricing system.

One way of understanding the role of economic regulation is to distinguish between the *absolute* level of prices and the *relative* levels of prices. Arguably the PPRS price and profit controls are aimed at regulating the absolute level of prices,

[8]The rebate for 2017 is 3.5% and the range for 2018 is between 2.5% and 7.5%

[9]The Association of the British Pharmaceutical Industry (ABPI) is the trade association for over 150 companies in the UK producing prescription medicines founded in 1891. This organization represents the views of the pharmaceutical industry to the government and decision-makers in the UK. Members include the vast majority of pharmaceutical companies in the UK, which negotiates between large and small companies that research and develop prescription drugs. Their members develop, research, produce, and supply more than 80% of the drugs prescribed by the National Health Service (NHS).

whereas Value-based pricing (VBP) is primarily aimed at trying to ensure relative prices reflect relative value. Clearly both aspects are important for economic efficiency, but different elements of regulation may be needed to achieve them. Where, as in the UK, regulation is also about procurement, then overall expenditure as well as absolute price levels are important.

3.2.1 Flexible pricing

Flexible pricing recognises that at the time of the initial launch, a medicine may not fully reflect its long-term value to patients in the NHS. This mechanism allows companies to increase or decrease original list pricing in light of new evidence or a different indication being developed. This more flexible approach is a natural consequence of taking a more value-based approach to pricing.

The potential for flexible pricing will apply only when medicines are subject to NICE appraisal. A review by NICE will be required to determine the new value to the NHS. For medicines not selected for NICE review, the potential to increase prices via modulation will remain an option.[10]

There are two circumstances therefore in which flexible pricing may be relevant: i) when significant new evidence is generated that changes the value of an existing indication, and ii) where a significant new indication is proposed.

Flexible pricing is intended to have minimal DH involvement and to be an "automatic" process. NICE can veto a UK price increase on an existing indication but not for a new indication (Towse, 2010; Baldwin et al., 2010). The price for a new indication could be higher than the price for existing indications, but the price of the original indication must remain the same.

Our understanding is that these PPRS arrangements have not been used. Given the increasing importance of multiple indication pricing and the collection of evidence post-launch, it will be helpful to revisit these arrangements.

3.2.2 Patient access schemes

PASs are designed to ensure patients can gain access to medicines which might not be deemed cost-effective by NICE. They are agreed between the DH and the company to improve the cost-effectiveness of medicines. They can be proposed at the start of a NICE review or after NICE's provisional assessment, if a drug is not recommended.

The experience of PASs introduced in the PPRS 2009 led to the development of a typology for PASs in 2014. In the one hand, there are simple discounts schemes

[10] To our knowledge, no applications have been received under the flexible pricing mechanism.

that must meet the simple discount criteria which ensure that a PAS imposes no significant ongoing additional data collection on the NHS. The other option for a scheme would be to change the list price of the product. On the other hand, there are complex schemes that include all other types of PAS. This could potentially incorporate a wide range of models including rebates, stock supplied at zero cost, dose capping, and outcome-based schemes. In contrast with simple discount PAS, complex PAS may be specific to one or more indications of a medicine. However, a PAS should only modify the cost of a single product.

Most PASs are simple discount schemes. Experience with PAS since the 2009 PPRS showed that complex schemes can be burdensome for companies and the NHS because of the poor quality of routine NHS data collection, requiring bespoke arrangements to be put in place. Given the importance of collecting evidence and tackling the uncertainty around value at launch, it will be important to revisit these arrangements. This need is compounded by the move by NICE and NHSE to introduce Managed Access Agreements for some oncology drugs under the revised CDF arrangements and some HSTs.

The 2010 Coalition Government included a commitment to move to a system of value-based pricing (VBP) in its programme "*the Coalition: our programme for government*".[11] In 2013, after having failed to develop a form of VBP itself, the Government gave NICE the task of developing methods for value assessment under VBP to allow the consideration of wider factors in a more consistent, systematic, transparent and predictable way. NICE's proposals met resistance from many stakeholders and so it continued with its previous methods. The assessment of value is primarily but not exclusively driven by cost per Quality Adjusted Life Year (QALY) analysis. It is also based on a deliberative process that, in principle, takes into account other factors in order to come to a view on whether or not a treatment is likely to be cost-effective (Lauterbach et al., 2016).

3.2.3 Modulation

The PPRS allows price neutral modulation across the portfolio from 1 March 2014 of presentations on the market on 31 December 2013. This means that companies may adjust NHS list prices up or down to respond to commercial needs on the condition that there is no overall price inflationary impact on the NHS. Companies may seek to enter these arrangements for various reasons including the opportunity to gain market share at the expense of competitors.

[11] United Kingdom. HM Government (2010) The Coalition: our programme for government www.cabinetoffice.gov.uk/media/409088/pfg_coalition.pdf

3.3 The Statutory Scheme

The Statutory Scheme is the regulatory framework for branded medicines sold to the NHS for the non-members of the PPRS (the "Branded Medicines Prices Regulations"). It is based on the National Health Service Act 2006 (hereafter referred to as the NHS Act 2006).

The Statutory Scheme applies to around 10% of branded medicines. Like the PPRS, it sets an exemption for companies whose sales of branded medicines are less than £5 million in a given year. It also has an exemption for very low cost medicines where the list price is less than £2.

There is no direct comparison between the voluntary and the statutory schemes. As noted above, the 2014 PPRS is based on a payment mechanism: companies make payments back to the Department of Health based on their sales of branded medicines to the NHS. By contrast, the Statutory Scheme is a method of price control, not revenue or profit control. It operates on the basis of a cut to the published 'list' price of branded medicines, not a net (transaction) price cut – which has important implication for savings achieved, as discussed in Section 3.

The lack of a long-term agreement means that the Statutory Scheme does not provide stability since the government can revise it at any time. Indeed, the EU Pricing Transparency Directive requires it to be reviewed each year. Potentially, new price cuts can be introduced each year. There is also no option for companies to modulate prices. It also does not provide a framework for a more comprehensive agreement between the pharmaceutical industry and the government, covering the assessment of new drugs, access, innovation and life sciences policy.

The Government has recently legislated to change the powers it has in relation to the design and coverage of a statutory scheme, and it is discussed below.

3.3.1 The Health Service Medical Supplies (Costs) Act

The Health Service Medical Supplies (Costs) Act (hereafter referred to as *the Act*) had its First Reading on 15 September 2016 and received Royal Assent on 27 April 2017. The Act made a number of amendments to the National Health Service Act 2006 on matters related to the control of medicine prices to address a number of concerns that the Government has expressed. Two observations are of relevance for our analysis. For branded medicines, the Act provides powers for the Secretary of State for Health to make changes to the statutory scheme to make it more aligned with the 2014 PPRS. For the unbranded generic segment, the Act controls the prices of unbranded generic medicines and requires all medicines manufacturers and suppliers to provide information relating to net prices. The aim of the reform is

to enable government to introduce price regulation of all prescription drugs (both branded and generic) and provide an additional control option.

Since 2014, the Statutory Scheme appears to have delivered lower savings for the NHS than the PPRS.[12] This is explained, in part, by the differences between list prices and net prices for medicines. The cut in list prices the Statutory Scheme applies is not effective when companies are already discounting heavily from the list price. As a consequence, some companies switched to the Statutory Scheme, reducing PPRS savings. However, the other complication is the impact of the new Hepatitis C treatments which increased drug bill growth rates. Gilead, the market leader, is not in the PPRS. It has also been heavily discounting, in part due to the use of tendering by NHSE. Had all of the companies in the Statutory Scheme been in the PPRS it is likely that the rebate scheme would have generated more savings for the DH than the Statutory Scheme price cut. This cannot be concluded definitely in the absence of knowledge about the level of discounting. What is clear is that the growth in drug spend by medicines in the Statutory Scheme has been unpredictable and a problem for the DH.

The Act amends the NHS Act 2006 to clarify that the Secretary of State can modify the statutory scheme for the purpose of safeguarding the financial position of the NHS by ensuring that the costs of branded medicines supplied by companies in the statutory scheme can be controlled in a similar manner to the 2014 voluntary PPRS.

After a public consultation in the autumn of 2015, the Secretary of State concluded that replacing the 15% list price cut imposed by the statutory scheme with a payment mechanism on sales would deliver the largest savings for the NHS and also better align the way the statutory and the voluntary schemes work. This reform would enable the DH to put more effective controls in place, increasing the levels of savings on health service medicines covered by the scheme.

The Act would also allow the Secretary of State to make regulations to limit prices of, or profits relating to, unbranded medicines. Currently, the Government cannot apply price controls to the unbranded medicines on those companies who are members of the PPRS. The Act would remove this loophole. The Government does have the power to introduce price controls for companies in the statutory scheme, although to date it has not introduced these controls.

Finally, the Act would allow the Government to require all manufacturers, suppliers and distributors to keep and supply information to the Secretary of State on

[12] Department of Health. Annual Report, 2016. Available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/629984/DH_annual_accounts_2016_2017_web_version.pdf

medicine prices and sales (and also other information related to discounts or rebates, revenue or profits).

3.4 Pricing of unbranded generic medicines

The Government's current policy on unbranded generic medicines is to allow generic manufacturers and suppliers freedom of pricing for their products, relying on competition to keep prices low. The Government then claws back some of the discounts that pharmacists get from buying low cost generics. Nevertheless, the DH can intervene where market mechanisms have failed to protect the NHS from significant increases in generic prices and expenditure.

On 29th June 2005, details were announced of two voluntary schemes for generics manufacturers and wholesalers (Scheme M and W, respectively) backed by Section 33 of the Health Act 1999. Scheme M is a voluntary agreement between the DH and the British Generic Manufacturers Association (BGMA) representing the generic medicine industry. A similar scheme, Scheme W, is a voluntary agreement between the DH, the British Association of Pharmaceutical Wholesalers and the British Association of Generic Distributors representing the British generic pharmaceutical wholesaling industry.

All companies supplying generic medicines are able to join the relevant voluntary scheme. Those that decide not to do so shall be subject to a statutory scheme, which governs the price that may be charged for NHS medicines and the level of profit derived from their sales. Financial penalties are allowed in case that a supplier of NHS medicines fails to comply with the requirements of any statutory scheme.

One of the biggest changes as a result of the introduction of Schemes M and W is that companies that participate in Schemes M and W submit quarterly information relating to *net* sales and prices of medicines to the DH i.e. including discounts. The department uses this information to assess reimbursement prices. The DH sets reimbursement prices according to a formula that manages the profit margins made by pharmacists from dispensing generic medicines (BGMA website). The use of average prices among manufacturers to set reimbursement prices maintains the incentives for individual pharmacies to procure generic drugs efficiently, by seeking to secure a price lower than this average price.[13] Reimbursement prices are monthly published in the Drug Tariff. The Drug Tariff is produced by the NHS Prescription Services on behalf of the Department of Health.

[13] However, if all pharmacists get very high discounts, the reimbursed price will be lowered accordingly, so in the long run the incentives to get very high rebates might be counterproductive for pharmacists and companies.

The DH monitors more closely the market for unbranded generic medicines after the introduction of Schemes M and W. Nevertheless, most of the regulation of unbranded generic medicines is "ex post" relying on competition law. The Competition and Markets Authority (CMA) is responsible for investigating and acting when a company has been accused of misconduct, mainly referred to potential pricing abuses – and this applies to all consumer markets, including the market for unbranded generics. The analysis is case by case.[14] Section 4.8 discusses in more detail the use of competition law in the UK pharmaceutical market.

The DH have reported that there are limitations with how the market of unbranded generic medicines is regulated. There are two major concerns. The first one is regarding those companies that participate in Schemes M and W: given that these are voluntary schemes not all companies submit information, which means that the information received is inconsistent and not fully representative of the industry. The second one, and more important one, is regarding the whole unbranded generic medicines industry: there have been a number of high profile examples of significant price increases in the last years, which reflects the fact that relying on competition does not always work to keep prices low. Issues arise in particular if the numbers of suppliers of a drug are low. The Health Service Medical Supplies (Cost) Act is seeking to resolve these two issues, among others, as explained above, by (i) giving the DH the power to request information and (ii) giving it the power to set unbranded generic prices.

3.5 The role of NICE

The National Institute for Health and Clinical Excellence (NICE) is a Non-Departmental Public Body accountable to Parliament, initially established in England and Wales to help the NHS meet three continuing objectives: (i) to improve continually the overall standards of care; (ii) to reduce unacceptable variation in clinical practice; and (iii) to ensure the best use of resources so that patients receive the greatest benefit. It is the body charged with responsibility for deciding whether healthcare technologies referred to it for review should be available on the NHS in England and Wales. The All Wales Medicines Strategy Group also makes some decisions for the NHS in Wales. Generally it follows NICE decisions. Scotland and Northern Ireland have separate arrangements.

NICE was created in 1999 with the aim to ensure that patients benefit from innovative cost-effective drugs that are of value to patients. The NICE process and the PPRS are indirectly linked as companies consider the likely outcome of

[14] We present some cases in Subsection 3.3.

NICE appraisal when setting the price of a drug.[15] NICE uses a cost-effectiveness threshold of £20K per quality adjusted life year (QALY), rising to £30K when other factors are deemed relevant and to £50K in the particular circumstances of "end of life" treatments. This acts as an indirect form of price control via a price per unit of health gain as measured by the QALY. There is a separate Highly Specialised Technology (HST) programme which has not operated a cost-per-QALY threshold until a rule change introduced this in April 2017, with a threshold of £100,000 to £300,000.

Technologies recommended by NICE in its technology appraisal programmes must be funded by the NHS, by law, through the 'funding directive'. Normally, when the funding directive is applied, the NHS has 90 days to make the treatment available (National Institute for Health and Care Excellence, 2017).

The 'funding directive' exerts pressure on the NHS to find the money to fund a new drug or treatment that has been deemed as cost-effective by NICE, regardless of other priorities. This reflects the fact that NICE has found the drug to be cost-effective, unlike most activities undertaken by the NHS which have not had their cost-effectiveness reviewed by NICE or anyone else. However, when the budget impact is high, the NHS may require time to search for new arrangements to finance the required expenditure.

The funding directive has been compromised however by NICE and NHS England introducing from 1st April 2017 a 'budget impact test', to assess the level of the affordability challenge that new drugs or treatments pose. The test will look at the net budget impact of new products which will be replaced by the new treatment. For those products that have a net budget impact of £20m or more per year, in any of the first 3 years of its use in the NHS, a commercial discussion will be triggered between NHS England (NHSE) and the company. If these negotiations cannot resolve the budget impact challenge, the second step would be to phase the cost of introducing the new treatment over a longer period. NHS England will need to set how the phasing would work, informed by clinical advice, and the plans for reaching full implementation (up to 3 years). NICE will then consult with patient and professional groups and the company on the proposals. This new mechanism has received significant policy and media attention, as "affordability" is not included in NICE's remit. The pharmaceutical industry recognised the need for an adjustment period but argued that a budget impact of £100m was a more sensible limit. The £20m level might lead to frequent discussions/negotiations between NHSE and companies

[15] Of course, as mentioned above, the PPRS introduces references to NICE, for instance via the use of PAS and FPs.

and risks replacing NICE's value assessment and indirect price control with product by product bargaining between the company and NHSE.

3.6 The role of NHS England in procurement

NHS England (NHSE) is an executive non-departmental public body of the DH. Its role is to oversee the budget, planning, delivery and commissioning medicines and services for the NHS in England as set out in the Health and Social Care Act 2012.

NHSE is responsible for the direct commissioning of services outside the remit of clinical commissioning groups (CCGs), namely primary care, public health, offender health, military and veteran health and specialised services.

It impacts most directly on the economic regulation of the pharmaceutical sector in the area of specialised commissioning in two respects.

Firstly, in relation to Commercial Access Agreements and Managed Access Agreements, for drugs in the new CDF process of conditional use, for some HSTs, and, most recently, for drugs whose budget impact exceeds £20m per annum in one of the first three years. The issue here is now to build engagement with NHSE into the NICE timetable and to operate it in such a way that it does not compromise NICE's appraisal and guidance timetable or compromise NICE's scientific integrity and use of a threshold value of health gain.

Secondly, NHSE operates a procurement process. The procurement process operates at national or at regional levels. Effective procurement is an essential component of commissioning improved services and outcomes for patients and communities and ensuring value for money. The CCGs, but mainly hospitals and local procurement partnerships[16] have the role of local procurement for regional medicines and services.

Three main stages compose a procurement process for healthcare services. First, it is important to evaluate whether to use an existing contract or a procurement process to secure the provision of the services. If procurement is the option chosen, the decision is whether to conduct a competitive tender, or whether to allow patients to choose from any qualified provider. Second, once a decision to procure services has been made, it is important to signal to providers that there will be an opportunity open to them. Third, the procurement has to be conducted and a final decision taken.

This process can be long, tedious, and quite expensive, and it does not guarantee that the gains obtained from a good contract will outweigh the costs of having carried it out. The gains from procurement might be limited, especially if there are other

[16] The procurement partnerships are founded and funded by NHS organisations. Members work together to make the most of their purchasing power to maximise money available for patient care.

regulatory devices already playing a significant role in determining the total cost. Indeed the role of NHSE in procurement is, at some point, overlapping with the PPRS. If NHSE is successful in using its bargaining power to get high discounts, this will affect pharmaceutical industry revenues which, in turn, will trigger a downward adjustment to the "PPRS payment" being made by industry back to DH.

The gains from procurement depend on (i) the bargaining power on the NHSE side and (ii) the degree of competition on the supplier side which will determine the bargaining power of the suppliers. It is not obvious that a comprehensive procurement process would provide more savings to the NHS than a negotiated PPRS. Clearly in some areas – such as treatments for Hepatitis C, NHSE was able to use competition to lower prices. One of the suppliers, Gilead, is not in the PPRS but in the Statutory Scheme, thus any procurement savings would not be offset by reduced payments under the PPRS.

3.7 The role of the Competition & Markets Authority (CMA)

Competition law seeks to curb practices that would undermine or restrict competition to the detriment of consumers: the abuse of a dominant market position by a firm, anticompetitive agreements between firms, and, mergers or takeovers which, if allowed, would result in a substantial lessening of competition.

In the UK the responsibility for enforcing competition law lies with the independent competition authority: the Competition & Markets Authority (CMA). The CMA was established from the merger of the Office of Fair Trading (OFT) and the Competition Commission (CC), and took on these duties from 1 April 2014. The legislative framework for the UK regime is established by the Competition Act 1998 and the Enterprise Act 2002, as amended by the Enterprise and Regulatory Reform Act 2013 which created the CMA. This framework gives the competition bodies a great deal of independence from Government. The Government has very limited powers to intervene in either the assessment of mergers or the investigation of markets. The DH can bring cases to the attention of the CMA and does so. In the event of the CMA finding a company in breach of competition law, the DH can seek to claim damages in the civil courts for any adverse impact on the NHS it believes has arisen from that breach. This is in addition to any fines levied by the CMA on the company. However, competition law operates ex post, i.e. investigations take place after the abuse has occurred, thus there is a long delay before DH is likely to get any sort of financial redress. Hence, it is likely to seek to use policy levers of its own when they can achieve a more immediate effect, using the CMA as a fallback. The CMA is, however, entitled to investigate potential anti-competitive behaviour

in the supply of medicines to the NHS irrespective of the views of the DH.

The PPRS is occasionally referred to in the context of competition disputes that involve pricing of pharmaceuticals (either branded or generic) and the OFT did carry out a Sectorial Market Study on the PPRS. The fact that a pharmaceutical company is subject to the PPRS does not exempt a company from being investigated and ultimately, if it is the case, being found guilty of anticompetitive practices (and fined accordingly). The first case brought forward against a pharmaceutical company after the introduction of the 1998 Competition Act was in 2001. Napp Pharmaceutical Holdings Limited was penalised for using predatory pricing in the supply of sustained release morphine (MST) tablets to hospitals, and for setting excessive pricing to UK patients in the community. Napp was found guilty of discounting heavily to capture the hospital market, in the knowledge that doing so would enable it to win a significant advantage in the out-of-hospital community market (Mestre-Ferrandiz, 2006).[17] In making this decision, the OFT confirmed that it is not the aim of the PPRS to monitor if individual prices are appropriate or lawful from a competition law perspective. The PPRS only analyses overall return on costs and sales, and Napp was not in breach of the PPRS.

The second case involving a pharmaceutical company happened in 2003. Genzyme was found guilty by the OFT of abusing its dominant position in the homecare market for the supply of drugs for the treatment of Gaucher disease. There were two charges of abuse of a dominant position by Genzyme, i) bundling abuse, after charging the NHS the supply of the product and the provision of homecare services, and ii) margin squeeze abuse, precluding viable competition by charging third party homecare service providers a price that did not allow them to get a reasonable profit margin[18]. Similar to the Napp case, Genzyme was fulfilling the requirement of the PPRS but was not exempt from investigation and possible infringement.

The PPRS has also been under discussion in relation to a recent case of de-branding, which resulted in the CMA imposing a fine on Pfizer of £84.2m and a £5.2m fine on the distributor Flynn Pharma, for overcharging the NHS. The fines follow an overnight price increase by Flynn Pharma of 2600% for phenytoin sodium capsules, a drug that is used in the treatment of epilepsy, in September 2012. Before that date, Pfizer manufactured and sold the capsules to UK wholesalers

[17] The argument the OFT used was that this was predatory against companies who only competed in the hospital market. It is not clear that this decision was helpful to the NHS. It forced companies to review their policies on discounting prices to hospitals. If discounts were subsequently reduced to avoid being accused of predation by the OFT, the NHS will have ended up paying higher prices.

[18] Whilst understandable in terms of competition principles, it is not obvious that the NHS benefited from improved competition in the homecare market.

and pharmacies under the brand name Epanutin, and the prices of the drug were regulated by the PPRS. In September 2012, Pfizer sold the UK distribution rights for Epanutin to Flynn Pharma, which de-branded (or 'genericised') the drug, meaning that it was no longer subject to price regulation. Pfizer continued to manufacture phenytoin sodium capsules but supplying to Flynn Pharma at prices that were significantly higher than those at which it previously sold Epanutin in the UK. Flynn Pharma then sold the product at higher prices. The CMA found that both companies have held a dominant position in their respective markets and each abused that dominant position by charging excessive and unfair prices. The case is still open because Pfizer and Flynn Pharma are asking the Competition Appeal Tribunal to repeal the CMA's decision, saying that they have been wrongly identified as 'dominant in the market'.[19]

With regards to generic pricing, the CMA has also taken action against pharmaceutical companies. In 2016, GlaxoSmithKline plc (GSK) was fined £37.6m by the CMA over pay-for-delay deals that held back sales of cheaper, generic versions of its branded paroxetine, an anti-depressant called Seroxat. GSK was found guilty of agreeing to make payments and other value transfers totalling over £50 million to suppliers of generic versions of paroxetine. Pay-for-delay agreements defer the competition that the threat of independent generic entry could offer, and potentially deprive the NHS of the significant price falls that generally result from generic competition.[20] When generic entry eventually took place at the end of 2003, average paroxetine prices dropped by over 70% in two years.[21]

3.8 Issues in the current regulatory environment

As we have seen, many regimes and actors play a role in the UK's regulatory ecosystem. So far, we have detected several key points that are crucial when trying to understand the functioning and the effects of the current economic regulatory environment:

- The importance of a PPRS as a regulatory and procurement bargain that covers a number of objectives beyond the immediate price and budget impact of medicines;

[19] As this is a current investigation we do not comment further.

[20] The issue in "pay for delay" cases is distinguishing between payments to get rid of aggressive litigation which consumes company time and resources and payments to delay entry.

[21] Is the Current UK System of Pharmaceutical Price Regulation Working? [Online]. Hausfeld, Global Litigation Solutions. Available at https://www.hausfeld.com/news/eu/is-the-current-uk-system-of-pharmaceutical-price-regulation-working.

- How well the current expenditure cap is perceived to have worked for industry and for the DH and (in England) the NHSE?
- The question as to the future role of the ROC/ROS profit control element of the current PPRS which appears to be becoming redundant;
- The importance of the PPRS covering the arrangements around NICE, which through its cost-per-QALY threshold is indirectly setting net prices for new drugs;
- The need to regularise the arrangements for NHSE getting involved in the NICE decision making process. Irrespective of the level of budget impact chosen, the NHSE involvement needs to be structured in such a way that it is not sequential and so delays access for new drugs. Arguably NICE needs to manage this as part of its process. Such a process could also be used for the CDF agreements when a commercial access agreement is needed. While NICE needs to manage it, it also needs to ensure its own scientific integrity is not undermined;
- The need to revisit the flexible pricing arrangements which do not appear to have worked well, and to recognise the efficiency (in terms of prices reflecting relative value) and access gains that could come from pricing by indication and by patient subgroup;
- Given the use of observational data in CDF conditional approvals it may make sense to revisit the potential use of more complex PASs or other performance based agreements.
- The need to avoid regulatory overload. The current mechanisms of control seem to involve duplication and overlapping controls. For example, there is an overall aggregate revenue growth rate cap, as well as NHSE procurement designed to reduce drug prices. Arguably this is duplication. NHSE procurement efforts will simply reduce the size of the rebate under the growth cap.
- The potential relevance of competition. Arguably some therapeutic sectors are highly competitive and no further price regulation is required. However: (i) the desire of the DH for a stable procurement arrangement may make such an arrangement difficult; (ii) it also moves away from a portfolio control approach; and (iii) it still requires some element of value assessment for new entrants into the therapy area.

4 International experience of Pharmaceutical Regulation

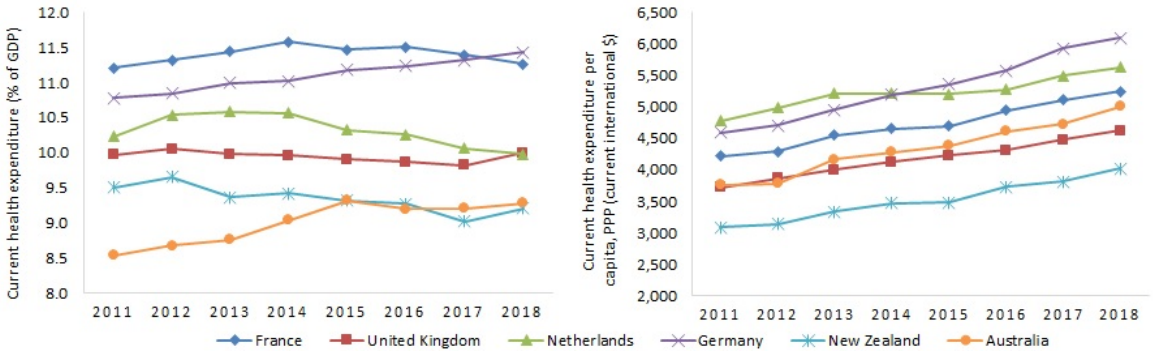
4.1 Regulation in Five Countries

In this section we briefly present the pharmaceutical regulation framework of five countries: France, the Netherlands, Germany, Australia, and New Zealand and identify relevant issues for the UK. These five countries were chosen as relevant for different purposes, representing a wide range of options.

In the case of Germany, it was the first country to formally adopt therapeutic reference pricing, in 1989, followed by the Netherlands in 1991 and New Zealand in 1993. It uses a therapeutic added value and price negotiation approach for products that are not reference priced. This can involve the use of international reference pricing. It should be noted UK prices are widely referenced by countries using international reference pricing. France also uses a therapeutic added value and price negotiation approach, but this now includes a cost-effectiveness study. It also uses international reference pricing, and a system of contracts between the Government and individual pharmaceutical companies. The Netherlands has a policy mix of cost-effectiveness, external reference pricing, price caps, and similar treatment for branded and generic medicines. New Zealand is a small country that has succeeded in achieving low prices for pharmaceuticals, reflecting the government giving PhARMAC a relatively low fixed budget and monopsony power to negotiate price cuts. Finally, Australia together with the UK, doesn't use reference pricing as a main tool to set pharmaceutical prices, but a form of cost-effectiveness analysis overseen by the Pharmaceutical Benefits Advisory Committee (PBAC). It uses a system of contracts (price-volume agreements) between the Government and individual pharmaceutical companies to underpin PBAC recommendations. It recently introduced a measure imposing price cuts after a new product has been on the market for 5 years.

We observe in Figure 1 data on health expenditure in each of the selected countries, including the UK. The left panel shows the current health expenditure as a percentage of GDP from 2011 and 2018 (the last year available). The UK allocates about ten percent of its GDP to health since 2011. France and Germany show the highest shares, similar between each other in 2018 (between 11% and 11.5%), and New Zealand and Australia show the lowest shares, also similar between each other in 2018 (between 9% and 9.5%). While the Netherlands showed a higher share than the UK during the last decade, both countries approached the point that in 2018 the current expenditure was almost the same.

Figure 1: Current health expenditure (selected countries)



Data from database: World Development Indicators.

The similarity between the UK and the Netherlands in terms of current health expenditure as a percentage of GDP vanishes as we look at the value per capita, PPP. The right panel in Figure 1 shows the current health expenditure per capita in the same years. The UK has the lowest current health expenditure per capita PPP since 2011, right above New Zealand.

The UK is the seventh largest pharmaceutical market in the world (IQVIA website)[22], and is the only country among the selected ones that does not use reference pricing. In Europe, the only other country that does not use (either formally or informally) reference pricing is Sweden. Germany now has the option of using international reference pricing as an option, after implementing the AMNOG law (see Appendix 1 for details). Many other countries refer to UK prices when using international reference pricing. They also look at NICE and SMC decisions. This means that, even though the UK is not that large in sales revenue, it plays a major role in pricing in other, larger, markets (see Appendix 1 for more details).

Germany is the fourth largest pharmaceutical market in the world, following the United States, China, and Japan. The law introduced in 2011 (AMNOG) changed significantly the functioning of the Germany system, and among other things, allows for price revisions after evaluation. For new in-patent drugs, the innovator may introduce the product at an initial price of its choosing (as before) for the first twelve months. Then, there are three options: the price is subject to (i) a rebate agreement if the drug has been deemed not to have enough therapeutic value, (ii) international reference pricing if no agreement can be reached, (iii) therapeutic reference pricing if it is deemed there is no evidence of added value. Not all drugs are assessed (the

[22] https://www.iqvia.com/-/media/iqvia/pdfs/canada/2019-trends/top10worldwidesales_en_19.pdf?la=en&hash=5B6D9922E053B42D9F2A1FD7A1883A87

company decides if it wishes to seek a higher price than existing drugs in the therapy area) and drugs for use in hospitals are not assessed. If the drug is not assessed, prices are set by therapeutic reference pricing, including generic alternatives.

In the Netherland, there are three lists. Annex 1A includes therapeutically interchangeable products, including generics, which are reimbursed according to the reference price system. The clustering is done according to the ATC code (a mix of 3, 4 and 5). Annex 1B contains unique medicines, which cannot be clustered with other medicines, and maximum prices for these drugs are based on international reference pricing (using Belgium, Germany, France, and the UK) and revised every six months. A comparable product should be marketed in at least two out of the four countries, where a comparable product is a product with the same substance, including brands, generics, and biosimilars. The average of these prices will be equal to the maximum retail price in the Netherlands. However, buyers could get discounts on those prices. Conditions for including a medicine in Annex 1B are based on an assessment of the therapeutic value and cost-effectiveness. Annex 2 includes medicines only reimbursed under specific circumstances, for example if prescribed by a specialist, if administered within a specialised healthcare centre (e.g. for cancer treatment), or after approval by the health insurer.

In France, in the case of the out-patient market, only prescription-only pharmaceuticals are reimbursed, and the ex-factory price[23] and the retail price are both regulated. Regulated prices are negotiated between the company and the Healthcare Products Pricing Committee (*Comité économique des produits de santé,* CEPS). All new drugs are evaluated, and two "grades" are given, on absolute medical value (which determines co-payment rate) and added medical value (ASMR), which is a key factor in determining prices. If a new drug is considered as of moderate to high added therapeutic value, a minimum price is set for five years using international reference pricing. It will not be lower than the lowest price observed in Germany, Italy, Spain, and the UK. There are no maximum prices for drugs. A small proportion of medicines are usually deemed as having a high relative medical value. If a new drug is considered as of no or low added therapeutic benefit, negotiations are based on the price of the most appropriate comparator drug, and also on international reference prices. In addition, the Government negotiates contracts with companies which agree expected revenues and rebates across the companies' portfolios.

Prices for generic drugs in France are determined by the Government based on a fixed proportion of the originator price, set through negotiation with the indus-

[23] Ex-factory price refers to the cost a manufacturer charges for a distributor or other buyer to purchase products directly from the source. It does not include shipping, handling or taxes.

try. For generics with insufficient penetration into the market, an internal reference pricing system applies. In the case of pharmaceuticals sold in the hospital market, prices are freely negotiated subject to public procurement rules.

In New Zealand prices are determined by negotiation with PHARMAC, an effective monopsony purchaser who manages the budget, negotiations, and prices of pharmaceuticals. However, pharmaceutical price controls are not used. PHARMAC takes reimbursement decisions based on a variable annual budget, and on a relative ranking of medicines that are funded according to their position on the list that reflects the cost-effectiveness analysis. Reference pricing is used to set government subsidies for medicines in the same therapeutic group. When a new drug is released, it is subsidised only if it offers a price below the prevailing reference price in the group. When the drug is not clusterable, PHARMAC and the manufacturer negotiate the price. Similar to the UK, there is a chance to modulate prices. Cross-therapeutic deals are possible, which means that the manufacturer is allowed to set a higher launch price in a new drug if it reduces the price of another of its products. These deals allows PHARMAC to negotiate lower prices with other companies who offer their products in the same therapeutic area.[24]

In Australia, prices are set by negotiation between the government and the companies. The Government subsidises the cost of many medicines for Australians through the Pharmaceutical Benefits Scheme (PBS). Applications for PBS listing are considered by the Pharmaceutical Benefits Advisory Committee (PBAC), which is an independent expert body appointed by the Australian Government. The PBAC bases its decision on cost-effectiveness or 'value for money' of the new medicine when compared to existing treatments, and it uses a Health Technology Assessment (HTA) methodology to evaluate applications. Expenditure on the PBS is uncapped, however, the budget is subsequently revised downwards to a relatively flat level of spending (as seen in Figure 1). This downwards revision is due to the 2015 PBS Access and Sustainability Package of reforms, which is lowering the price the Government pays for many medicines. It also reflects the ongoing impact of price disclosure policies, which are designed to move the PBS price paid by the Government closer to the market price of off patent medicines (which may be heavily discounted).

[24] This strategy is particularly attractive to PHARMAC when there is a high asymmetry of market shares of companies operating in two different therapeutic areas. Company A finds attractive to increase the price in one market where it has a high market share in exchange of reducing its price in a market where it has a low market share. Then, it enables PHARMAC to negotiate lower prices in the second market with Company B that is the one that has a high market share.

4.2 Regulatory Options from the Five Countries for UK Regulation

From the previous section, we know that several options might be considered when analyzing alternative options to the PPRS. After considering all these options, we selected the ones that are the most attractive for the UK.

4.2.1 Therapeutic Reference Pricing (TRP)

The price of a drug is set in comparison with other drugs in the same class, with potential mark-ups for improved efficacy, better side effect profile or convenience, for example. The reference price does not necessarily become the market price, but rather a benchmark price. Manufacturers might be able to set higher prices than the reference price, but in doing so, competition with equivalent, lower-priced medicines will be tougher. This is the case of Germany, where drug companies can set higher prices but payers only reimburse up to the reference price, and patients need to pay any difference out of pocket. Pfizer tried to do this with Lipitor but was not successful. In other countries, such as in the Netherlands, the reference price is a maximum price and firms are not allowed to sell at a higher price. New Zealand has an intermediate position. Manufacturers can set a price above the reference price, but they lose all subsidy if the product cannot show to provide additional clinical benefit than a substitute available at a lower price.

TRP essentially regards medicines within a therapeutic reference group as interchangeable, and having no differential value. This should be a matter of fact, not an assumption. It can be differentiated from a situation in which a payer seeks to use tendering for products for groups of patients and then looks at whether any differences in prices offered are justified by differences in clinical performance.

With TRP, there are likely to be particular problems for new products that bring significant improvements to some patient sub-groups and should get a premium price for those indications. The ability to charge patients a higher co-pay is unlikely to be politically feasible in the NHS.

TRP is therefore likely to discourage follow-on innovation by reducing the potential returns to these products, and it also does not provide a mechanism to set a price for a first in class product – the key challenge for an innovation driven industry.

In summary TRP is a crude tool that is likely to have adverse effects on innovation and is not a particularly efficient form of economic regulation.

4.2.2 International Reference Pricing (IRP)

In words of Espin et al. (2011), international reference pricing can be defined as "the practice of using the price(s) of a pharmaceutical product in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country." Under this scheme, regulators need at the bare minimum to choose the group of countries in the basket, set the weights on each country and adjust for exchange rate (where relevant). New medicines could then be priced at the average (or lowest) of the reference countries – countries use different criteria. As we previously mentioned, in the Netherlands the average of the international price sets the maximum price allowed for a new medicine. In contrast, in France the lowest price observed internationally sets a minimum price for the new drug. This is because in France it is applied only to the more innovative medicines, using IRP is a means to ensure a 'reasonable' price.

There are some issues with this type of regulation. First, price information is not always available. Available prices are often heterogeneous (ex-factory, retail prices, etc.) and it is not always easy to adjust them to obtain the required type of price. Transaction prices will differ from list prices because of confidential discounts. Comparisons are vulnerable to changes in the exchange rate. Second, it is not easy to find exactly the same product abroad (strengths, pack sizes, etc.). Third, and most fundamentally, it makes the system dependent on the decisions of other regulators. In effect a country is out-sourcing its assessment of value. This may make sense for a small country, when comparators with larger countries with similar income-per-capita, health systems, and population characteristics are available, but not in other circumstances.

4.2.3 Health Technology Assessment: Cost- effectiveness Analysis versus Therapeutic Value-added

Drugs are assessed for use by looking at incremental health and related effects and incremental costs of a technology relative to existing treatments. All five countries have expert bodies in charge of a formal review of the effectiveness of some or all new drugs as a condition of reimbursement or of use. New Zealand, Australia, and the Netherlands focus on cost-effectiveness like the UK, while France and Germany focus on clinical effectiveness, or therapeutic added value. France and Germany then use this assessment as an input to price negotiation. Health technology assessment thus controls price indirectly.

The link is stronger, as in the UK, when there is an explicit cost-effectiveness threshold. In effect, there is a price for a unit of health gain. This form of price

regulation is more aligned with the principles of efficient resource allocation than other regulatory methods. It also, in principle, offers more efficient incentives for R&D provided the threshold is set at the right level.

However, this option presents at least three important unresolved details:

1. there are substantial difficulties in determining the cost-effectiveness of a drug at launch. Considerable flexibility around conditional use, price flexibility, and post-launch re-assessment is needed;

2. it requires a clear link between the cost-effectiveness and the willingness to pay for health gain by the public. This is difficult to assess, but also evidence suggests that the NHS is underfunded indicating that an opportunity cost-based cost-effectiveness threshold will be lower than willingness to pay[25].

3. the QALY requires qualification in three respects:

   (a) in some disease areas it may not be a good measure of health gain and so require being supplemented by other disease specific measures;

   (b) "a QALY is not a QALY" . Weighting is needed to reflect social priorities around treatments, for example reflecting disease severity. This requires a structured deliberative decision making process in which the social priorities are supported by evidence;

   (c) a broader definition of value is required beyond health gain.

Many in the global pharmaceutical industry prefer the sequential approach of France and Germany, with an initial focus on clinical efficacy evidence. However a sequential approach can lead to delays in reimbursement. This happens in France. In Germany the product can be reimbursed while the clinical assessment and subsequent price negotiation are taking place. Furthermore, if the clinical evidence is key then it may be used as a *de facto* form of price pressure with high evidence requirements. This has been the case with IQWiG, although the G-BA has been more flexible. Finally, although there is some evidence that prices are higher in France and Germany than in the UK, both countries spend much more per capita on health care than the UK. There would be no reason to believe that NHSE would operate a pricing policy that led to prices higher than those currently approved by NICE.

[25] The DH has in the past used £60,000 as the WTP for a QALY, as compared to £25,000 per QALY for NICE (an average of the £20,000 - £30,000 range.) DH economists are now arguing, in the basis of the York Report, that £15,000 is the NHS opportunity cost value of a QALY.

The use of cost-effectiveness cannot be sufficient as a form of economic regulation, because it is not appropriate to put all products (old and new) through a NICE or similar HTA review. Some sort of economic regulation is needed for non-NICE reviewed products.

4.2.4 A Fixed Drug Budget as per PHARMAC

PHARMAC operates a fixed pharmaceutical budget, which grows when the government is willing to allocate more money. PHARMAC operates rationing using cost-effectiveness analysis and deal-making with companies to try and make the most effective use of its money. As a result of its constrained budget, combined with PHARMACs efficiency, it is almost certainly the case that switching spending from elsewhere in the health budget to pharmaceutical spending would improve health outcomes for the NZ population. It shows, however, the potential risks of treating medicine spending as a silo to be managed and controlled separately from the rest of health spending.

The current PPRS control mechanism operates differently – as a rebate system – thus patients in principle get access to drugs. However, if the expenditure growth cap is too low, then company profitability and the returns to innovation will be hit.

4.2.5 Individual Company Contracting as in France

The French Government operates revenue cap and rebate agreements with individual companies. In effect the regulatory mechanisms are being applied at a company rather than industry level. It is the norm in the utilities sector that the regulators put a lot of effort into setting different price controls for each regulated company. However, reaching different agreements for different companies in the pharmaceutical industry has three complications:

1. The procurement element means that the DH and the NHSE are interested in aggregate expenditure across all companies.
2. Innovation is a key part of pharmaceuticals and is even harder to estimate at the individual company level over a 5 year period. This suggests that the contracts will be revisited at each product launch, or, de facto there is a contract for each product.
3. In the utility sector, managing the regulatory environment is a key driver of the business. The PPRS scheme is designed to minimise regulatory burden in order to enable companies to concentrate on running their businesses. Company

level contracting risks turning the management of that contract into a primary business purpose and increasing the burden of regulation for both parties.

We need to separate the concept of the regulatory contract for a portfolio from companies negotiating arrangements with NHSE around a particular product within the overall regulatory framework and within a NICE approval process.

Table 1: Price regulation in selected countries

	Type of regulation	Country baskets for International RP	Characteristics	HTA assessment	Reimbursement decision	Price determination	Who executes?	Reference group
UK	PPRS/Statutory Scheme	-	Maximum prices (both), maximum rate of return (PPRS)	NICE	NICE	New: free. Old: DH + industry (ABPI or companies)	Department of Health	-
Australia	Cost plus method, internal reference pricing, others.	-	Internal reference pricing: reimbursement at the lowest price in the groups. There is not a maximum price for others. Individual contracts fix prices.	PBAC	Ministry of Health	DH (and companies)	Department of Health	By therapeutic class
France	Therapeutic RP and international RP, as key criterion for innovative medicines	(4) Germany, Italy, Spain and UK	There is not a maximum price. Individual contracts fix prices.	Haute Autorité de Santé, HAS (Commission de la Transparence)	Haute Autorité de Santé, HAS (Commission de la Transparence)	Comité Économique des Produits de Santé, CEPS (and companies)	Haute Autorité de Santé, HAS	By active substance
Germany	Reference pricing, internal and external (as supportive information)	(15) Austria, Belgium, Czech Republic, Denmark, Greece, Spain, Finland, France, Ireland, Italy, the Netherlands, Portugal, Sweden, Slovakia, UK	Free price for new products (1 year). Maximum reimbursement amount for each cluster (econometric modelling).	Institute of Quality and Efficiency in Healthcare, IQWiG	The Federal Joint Committee, GBA	The National Association of Statutory Health Insurance Funds (and companies)	The Federal Joint Committee, GBA	By active substance, pharmacological class, and therapeutic class
The Nether-lands	Reference pricing, as main criterion	(4) Belgium, Germany, France, and UK	Fix maximum prices on the average official list price	Health Care Insurance Board, CVZ	Health Care Insurance Board, CVZ	Ministry of Health (maximum price) but there are private negotiations to get discounts.	Ministry of Health	By pharmacological class
New Zealand	Reference pricing, internal and external (informal)	(3) Austria, Canada, and UK	Subsidize the lowest price in the sub-group	PHARMAC	PHARMAC	PHARMAC	PHARMAC	By therapeutic class (subgroup)

Notes: Therapeutic class: it is based on therapeutic intent (antianginals, sedatives, analgesics, antidepressants, etc.) It also includes several pharmacological classes. They are not chemically similar, and they have different mechanisms of action. Pharmacological class: it is based on a mechanism of action and includes only drugs that have the same or similar mechanism of action. It describes a drug's properties in a specific way. All drugs have similar attributes (indications, mechanism of action, contraindications, etc.), but they may differ in dosages, for example. Active substance: is the ingredient in a pharmaceutical drug that is biologically active

5 Regulation in other UK sectors

In this section we look at the lessons for economic regulation from utility regulation in the UK. We draw primarily on telecoms and energy (gas and electricity), but also touch on water and airports.

5.1 The Development of the RPI-X Control and the Role of Repeat Regulation

The privatisation of British Telecom (BT) in 1984 reintroduced the regulation of private infrastructure companies in the UK, after nearly forty years of public ownership (Green, 1997).

Professor Stephen Littlechild, an academic who subsequently became the first regulator of the electricity industry, was asked to choose between two different schemes to regulate BT: i) setting a maximum rate of return on capital (ROC) to control BT's prices, or ii) imposing an output-related profits levy on BT at a rate that would fall as the company's output rose, giving incentives to increase the volume of services delivered and to reduce costs and prices in order to do this. Littlechild found issues with the two options proposed. First, he said that setting a maximum rate of return would discourage BT to produce efficiently. Second, because competition on the telecommunications sector was expected, a profits levy on BT would place it in a disadvantaged situation with respect to potential competitors. Hence, Littlechild proposed a third alternative: a price cap system. This was the one adopted by the government.

The price cap adopted was later known as the *RPI-X* system. The idea was to limit BT's prices in the areas where it was believed to retain excess market power. A weighted basket of BT's prices would then be adjusted by the increase in the retail price index, *RPI* (a standard measure of general inflation in the UK), and a factor X that was the expected impact of productivity increases.

Littlechild argued that this scheme would protect consumers by setting a maximum price increase, while giving BT some freedom to change the balance of its prices within the basket so promoting efficiency. It was also good for the regulator as a system that was quite easy to monitor. However, it was expected to be a temporary solution, as there would soon be further competitive entry into the industry.

Whether or not Littlechild "invented" *RPI-X* or not is open to some debate. What is important to mention is that this scheme was intended to regulate only one company, BT. Nevertheless, its influence became much wider, and the government adopted this scheme for initial regulatory approaches to all of the subsequent

privatised UK utilities.

In 2003, a conference was held in London to mark the 20th anniversary of the publication of the Littlechild Report on telecom regulation. In that conference, the UK model for infrastructure regulation was discussed. It seemed to be doing well, however there where two particular challenges for the future of the *RPI-X*:

1. when price controls are repeated at (say) five year review points, then price cap regulation and rate of return on capital (ROC) seem less like very different alternatives to being opposite sides of the same coin as estimates of acceptable ROCs are used to set RPI-X, and

2. regulation, especially price reviews, were becoming more bureaucratic and legalistic (Stern, 2014). Both of these challenges relate to the issue of repeat regulation.

Repeat regulation is needed because without it the degree of misalignment between costs and prices progressively increases. This divergence is due to changes in costs, but also changes in the efficiency of input usage. In competitive markets costs and prices are kept in alignment by the entry and exit of firms. The process guarantees that firms, in the long run, earn normal profits. But in monopoly markets (or partial monopoly markets) this is not true and the regulator has to realign costs and prices in each regulatory review.

As we previously mentioned, the *RPI-X* model was designed for the telecom industry for a limited time (5 years until sufficient competition could emerge in the sector), and then the price cap could be abolished. Price cap regulation was presented as a superior substitute to rate of return regulation. However, it was later recognised that in sectors where it would not be possible to create competition, for example in the water industry, RPI-X (termed RPI+K in water regulation) would need to be long lived and take account of infrastructure investment requirements.

Repeat regulation is more complex than static regulation. In 1986 Littlechild recognised that in deciding how far to revise X, the economic regulator needs to take into account both production methods and the investment programme. The scope of the reduction in prices is conditional to productivity and efficiency, and to capital expenditure as well. He wrote: *"So, permanent regulation is more complex than temporary regulation... It should now be evident that rate of return considerations are necessary implicit in setting and resetting X"* (Littlechild, 1986).

It is clear that repeating an RPI-X scheme has become essentially a form of forward looking, incentive based price-setting with a major rate of return element.

The repeat regulation created a need to formalise and make more explicit the methods of handling financial aspects, which in turn created more bureaucracy at price revisions.

The fundamental problem of information asymmetry in regulation becomes more complex with repeat regulation, given that new elements, such as reputation and signalling, need to be taken into account. Given the inevitable superiority of knowledge by companies of their own costs and potential efficiency, this is a major problem for forward looking regulation – the companies (but not the regulator) know "where (and why) the bodies are buried" (Stern, 2014). It creates a strategic game between the regulator and the regulated company, where the regulator wants to know the real future costs and potential efficiency of the firm but the firm, which has better information, does not have any incentive to disclose them.

5.2 Use of Yardstick Regulation

One of the solutions proposed for information asymmetry in repeat regulation in the UK is "yardstick" competition (Shleifer, 1985). Schleifer also tackled the lack of incentives for cost reduction of the rate of return regulation. While the RPI-X was the solution for Littlechild, yardstick competition was the solution proposed by Shleifer.

Yardstick regulation consists in comparing performance of different companies to emulate a competitive market, using mainly econometric benchmarking of efficiency levels. It uses data from regulated firms related to the inputs and outputs of their business to identify the shape of the cost function. Once the cost function of the most efficient operator is found, a benchmark for the industry can be defined and the rest of the firms should, in principle, be able to achieve. This type of regulation is attractive when there are a number of regulated companies to compare, but it is not possible to implement for single national networks like electricity transmission. In this case, an international statistical comparison is needed. However, international comparisons are difficult to interpret given the regional, political, and economic differences between countries.

From 2000 onwards, yardstick competition exhibited increasing problems as a solution to information asymmetry. Mergers reduced the number of comparator companies in some sectors. The remaining companies had strong incentives to show they were "special" so they could get a special treatment in the comparisons. There were many solutions implemented to avoid this technical issue, however in 2005 UK utility regulators turned to alternative methods (but maintaining econometric benchmarking as a supportive tool).

5.3 Information Revelation Devices

Since 2003 two other solutions were proposed to the problems of repeat regulation: i) Menu Regulation and similar Information Revelation Devices (IRDs), and ii) Direct Contracting or negotiated settlements. We discuss these in turn.

The economic basis of menu regulation is the theory of incentive compatible contracts as developed by Laffont and Tirole (1986, 1993). While the poor incentive properties of rate-of-return and cost-plus regulation had already been recognised, the Laffont-Tirole model highlighted a subtle problem with price caps: high-powered incentives imply large rents to efficient firms, which is very costly if public funds are raised by distortionary taxation, or if the regulator has distributional objectives.

In the simplified version of the Laffont-Tirole model[26], the regulated firm can be of two types: i) it can achieve a low marginal cost via spending relatively low fixed cost (low-cost type), or ii) it should incur in a greater fixed cost to achieve a given level of marginal cost (high-cost type). In this setting, the regulator can observe the firm's *realised* marginal cost, but cannot observe the associated realisation of the fixed cost. In other words, the regulator is uncertain about the amount of effort required to achieve any given level of marginal cost.

If the regulator uses a "high-powered scheme" (a fixed-price contract such as RPI-X), given that it has to guarantee the participation of the regulated firm whatever its type, it will have to set a high compensation to cover the costs of the high-cost firm. But, if the firm is the low-cost type, it will leave the firm with information rents[27]. On the contrary, if it uses a "low-powered scheme" (a cost-contingent contract, such as the cost-plus regulation) it leaves the regulated firm with no rents, but it also reduces the incentives to exert effort in reducing the marginal costs, whatever its type. Then, there is a trade-off between giving incentives to exert a high level of effort and reducing the size of the information rent.

In the model presented here, the low-cost firm has incentives to pretend being a high-cost firm to get information rents, whenever it is possible, which is a problem to the regulator that wants to minimise the size of the information rents. The solution is that the regulator offers a menu of contracts designed in a way that the firm has incentives to report its type truthfully.

In practice, menu regulation requires companies to choose the amount of input expenditure, capital expenditures (Capex) and operating expenses (Opex), that they need to meet mandated standards. Companies choose their required expendi-

[26] There are many variants of this model. We present the one that is more relevant to the examples presented below.

[27] The information rent is generated by the informational advantage of the firm over the regulator.

ture relative to a baseline proposed by the regulator based on outside appraisals. Companies make a choice between receiving a lower expenditure allowance but with a "higher-powered incentive" , or a higher expenditure allowance, but with a "lower-powered incentive" . Hence, the menu regulation provides incentives to companies to reveal their current and expected future costs by making choices on required future expenditure to meet mandated standards.

Menu regulation was introduced into UK regulatory practice by Ofgem in 2004 for electricity distribution companies and later extended to gas distribution, and then to electricity transmission. More recently, it has broadened the scope of the mechanism to include Capex and Opex as part of its Revenues Incentives Innovation Outputs (RIIO) controls. Also Ofwat, the economic regulator of the water industry in England and Wales, introduced menu regulation in 2009. The most interesting feature about menu regulation is that it is criticised as being too complex. However, no UK regulator that has adopted it has chosen to give it up.

Ofgem and Ofwat have also supplemented menu regulation with the introduction of other information revelation devices (IRDs) called "fast" and "slow-tracking" : good performers with strong business plans, good past record, and effective consultation with consumers achieve "fast-tracking" of the regulatory process. Conversely, poor performers get "slow-tracking" with tougher scrutiny.

5.4 Direct Contracting

Under direct contracting, the firm seeking access to an essential facility directly negotiates terms, including what they will be charged, with the infrastructure companies outside of formal regulatory hearings. In short, the aim is to negotiate on the level of X in RPI-X.

The argument behind the creation of negotiated settlements is that they provide a different philosophy of regulation, facilitating agreement instead of the regulator taking all the decisions. Littlechild argues that it brings competition as a process of 'rivalrous discovery' into utility regulation.

In the UK, a less 'hands-off' variant of negotiated settlements was used by UK airports regulator in 2009 and 2014, termed 'constructive engagement'.[28] However, the negotiations do not determine the regulatory outcome, and it is up to the regulator to decide how much weight to give to the direct negotiations (Stern, 2014).

[28] The Civil Aviation Authority asked the airports and the airlines to agree as much as they could in setting landing charges, the need for new investment, etc., in advance of the regulator finalising the price control.

5.5 The Telecommunications Market

As in the case of other utilities, the need for regulation in telecoms markets arises from the existence of an essential facility which would be excessively costly to duplicate. In the telecoms industry, the essential facility is the so-called local loop, which comprises the network infrastructure (i.e., buildings, copper/fibre wires, ducts, poles, etc.) which is close to end user premises. In the UK, most of the regulation in the fixed telecoms industry concerns the conditions of access to BT's essential facility of the local loop.

The UK regulator of communications, Ofcom, is in charge of defining the regulation of telecommunication markets. In accordance with the duties set out in the Communications Act, Ofcom only imposes regulatory measures where it has been established that competition is unlikely to lead to desirable outcomes. Given the dynamic and innovative nature of the telecoms industry, this involves conducting frequent market reviews to assess whether there is a need for regulation.

Although the rationale for regulating the telecoms industry is somewhat different than the pharmaceutical industry, both sectors have a number of common characteristics. Notably, as in the pharmaceutical industry, innovation now lies at the heart of the telecoms industry. In defining price regulation, Ofcom now often takes into account trade-offs between static and dynamic efficiency. The former pushes regulation towards incremental costs, while the latter leans towards deregulation or prices above incremental costs.

In the recent years the telecoms industry has seen intense debates regarding the best approach to regulation to encourage investments in new generation networks capable of delivering faster broadband speeds (like fibre optic networks). Traditional copper-based networks started to lag behind demand for greater broadband speeds and reliability. Hence, it became necessary to rethink mechanisms to encourage investment in faster networks. One important aspect in this discussion was to avoid interfering with the innovation process, and adopt technology neutral regulation. So rather than being prescriptive about investing in a certain type of technology, Ofcom sought to reward faster, better, broadband outputs.

In order to encourage BT (and rival networks like Virgin Media) to invest in new generation networks, in 2010 Ofcom decided not to impose a price cap on superfast broadband wholesale products (with speeds above 30 MB/s). This decision was based on the 'fair-bet' principle, which states that investments involving sunk costs and substantial risks may only be recovered if there is a period of pricing above incremental costs. However, other legacy broadband products, like slower copper-based broadband services, remained regulated at long-run incremental cost.

Such legacy products effectively acted as an anchor for superfast broadband prices, limiting to some extent the adverse effects of deregulation in the superfast segment.

Following the introduction of such regulation, BT invested heavily in improving its network speeds, and the majority of British homes now have access to broadband speeds of above 30 MB/s. However, most British homes have not yet got access to speeds of 100 MB/s (ultrafast broadband). In order to keep the pace of innovation, Ofcom is currently proposing to start regulating cost connections delivering speeds up to 40 MB/s, but to give BT price flexibility regarding faster connections. This proposed policy change is aimed at encouraging a new round of investment in faster networks capable of meeting future demand. The new proposals, reintroducing price regulation for older products, displays some resemblance to a post-patent expiry situation in which the ability of the company to get a premium price for its innovation is coming to an end.

In parallel to this debate, Ofcom has been analysing to what extent maintaining BT's vertical integration would be consistent with its duties to protect consumers. Openreach is a division of BT which controls the essential facility. It provides regulated access to both BT's downstream divisions and to its wholesale competitors. Sky, Talk Talk, and most other retail broadband providers (except for Virgin Media which has replicated the essential facility with its own fibre investment), buy Openreach wholesale services to provide retail broadband and voice services and to compete with BT retail. This created a concern that Openreach may not have the right incentives to provide good and reliable services to BT's downstream competitors. As a consequence, Ofcom considered whether there was a case for splitting Openreach and BT into different companies. After several negotiations, Ofcom and Openreach settled on an agreement which did not involve full separation, but involved substantially more independence from BT in Openreach's decision making. BT agreed to make Openreach a legally separate company with its own board.

5.6 The Energy Market

UK electricity and gas markets are privatised, and they are regulated by the Gas and Electricity Markets Authority, operating through the Office of Gas and Electricity Markets (Ofgem).

Supplying energy (electricity and gas) from sources to homes across the UK involves three different stages: generation/production, transporting/transmitting and distributing, and selling it to the customer. Similarly to the case of telecoms, the need for regulation in the energy industry arises from the existence of an essential facility: since it would not be viable for all energy producers to build their

own transportation/transmission and distribution network, they depend on access to the existing infrastructure. Electricity and gas are both transported via national transmission systems which are run as monopoly businesses and are therefore subject to price control regulation. In gas, the transmission system is a high-pressure network of pipes. In electricity, the transmission system is a high voltage grid of wires. Ofgem regulates distribution and transmission networks and manages the commercial tender process for offshore transmission projects. UK energy wholesale and retail markets are not regulated because it is assumed that there are enough competitors to guarantee a competitive market. Companies seek to obtain their own gas and/or electricity supplies, pay for use of the essential transportation and distribution facilities and then compete to sell to final consumers.

In October 2010 Ofgem published its decision to introduce a new regulatory framework, marking the conclusion of Ofgem's two-year review of the RPI-X price control. The review was called RPI-X@20, to reflect that the RPI-X regime was first implemented in the energy sector in 1990, following the privatisation of the gas industry in 1986 and of the electricity industry in 1989. As noted, the X-factor reflected a combination of expected efficiency improvements, capital investment requirements, and rewards or penalties for service performance.

Ofgem proposed a new regulatory model called RIIO (Revenue using Incentives to deliver Innovation and Outputs). It is an incentive-based framework that sets a constraint on the revenues that network companies can raise from customers during the price control period. The aim was to build on the successes of RPI-X by developing an adapted incentive framework to link revenues to performance to deliver environmental objectives and long-term value for money network services. There were two primary drivers of the review (Jenkins, 2011):

1. The changing nature of energy network services, reflecting the role of companies in delivering a sustainable energy sector, and

2. The need to tidy-up the RPI-X framework.

Regarding the first driver, because of their role in delivery of a sustainable energy sector, network companies need to make new and different decisions about their 'pipes and wires' businesses. This changes the nature of network decision-making which in turn has implications for incentive-based regulation, with an increasing focus on long-term service provision and a greater focus on future customers.

The second driver is a result of a repeat principal-agent game. In terms of regulatory cycles, data collection and monitoring has knock-on implications for technical

efficiency through the ratchet effect: companies have incentives to misreport the information they reveal in order to influence future price controls. RPI-X regulation tends to focus on allocative and technical efficiency (static benefits) rather than on dynamic benefits. This can end up in low rates of innovation. For example, the investment in a technology that involves high upfront costs for a couple of years in exchange for delivering higher quality of service at lower operating costs for the next two decades is not attractive for a company focused on a five-year regulatory cycle. It will probably choose not to invest in the new technology given the high costs in the regulated period (even when total costs for consumers would be lower over the life of the asset). The new regulation seeks to tackle this issue by changing the length of the price control from five to eight years, expecting to help companies to shift the focus onto the longer term.

Finally, in the old regulation, there was no focus on consumers, and companies focused their attention on the regulator only. There has been limited linkage between the standards set and consumers' expectations and preferences. The RIIO model moves to a much greater emphasis on incentivising delivery of outputs relating to the customer experience and the environment, with focus on consumer satisfactions, social obligations, etc.

5.7 Lessons from the Economic Regulation of UK Utilities for the Regulation of the Pharmaceutical Industry

Whilst the reasons for economic regulation of pharmaceuticals differ from those of the utilities, as we discussed in Section 2., some of the regulatory challenges are similar, for example: encouraging competition; improving outcomes for customers/patients; keeping prices down in a way that is both consistent with companies earning a reasonable return, and with encouraging product innovation and any necessary large scale investment.

The main regulatory device used in the utility sector is the RPI-X control which limits prices in the areas where companies retain excess market power. In its simplest form, a weighted basket of prices is adjusted by the increase in the retail price index, *RPI* (a standard measure of general inflation in the UK), and a factor X that was the expected impact of productivity increases. The control would typically be set for five years. Arguably the PPRS does have a form of RPI-X control for established products. These cannot be increased, in effect it is RPI-RPI, i.e. X = RPI. Modulation has the effect of creating a weighted basket of prices.

The challenge for an RPI-X control is how to deal with new products, i.e. innovation. A separate "control" is needed. Arguably in the case of the pharmaceutical

sector, NICE exercises that control on any substantial new innovation.

A second challenge for an RPI-X control is that repeat regulation is needed, the X has to be reset. Repeat regulation is more complex than static regulation. It is clear that in utility regulation, repeating an RPI-X scheme has become essentially a form of forward looking, incentive based price-setting with a major rate of return element.

One option to consider is whether to use the RPI-X approach given there is already a NICE led approach to constrain prices of new products.

Another tool used in UK utility regulation is "yardstick" competition. Yardstick regulation consists in comparing performance of different companies to emulate a competitive market, using mainly econometric benchmarking of efficiency levels. Arguably a form of this has already been used in the PPRS profit control, with the DH often benchmarking cost elements against industry norms in establishing allowable cost levels for the purposes of calculating profits. However, the downplaying of profit control in the current PPRS may mean that this no longer takes place.

Other, more recent, regulatory innovations are i) Menu Regulation and similar Information Revelation Devices (IRDs), and ii) Direct Contracting or negotiated settlements. These are not readily transferable to the pharmaceutical sector. A third innovation, however, RIIO (Revenue using Incentives to deliver Innovation and Outputs) is worth exploring. The aim was to build on the successes of RPI-X by developing an adapted incentive framework to link revenues to performance to deliver environmental objectives and long-term value for money network services.

6 Price Control Negotiation Processes in the Utility Sector

It is important to highlight learning from the utility sector on the conduct of negotiations between government and industry in a systematic and orderly framework.

The aim of this section is to identify some of the processes that UK economic regulators have developed to provide a structured and tiered approach to the setting of price controls, and to highlight some ways in which those processes might have relevance to the PPRS negotiations.[29] We should note that the process is driven by the regulator. It is very different to the current PPRS negotiation approach where both sides make proposals, and there is no pre-defined process for moving to a negotiated agreement.

6.1 Price controls in regulated sectors and indicative process

While there are some differences of terminology and in precise timescales, over time economic regulators have tended towards the same basic structural approach to the process of setting price controls. Most notably for current purposes,[30] price control processes in the energy and water sectors include the key steps set out in Table 1.

The form of the regulatory process illustrated in Table 2 has been developed in the multi-party contexts that arise in electricity distribution, gas distribution and water price controls. The basic hierarchical approach that is employed is straightforward and unsurprising: start by sorting out the objectives, guiding principles and the framework to be applied, and then build up from there until an overall package has been developed. Its value, though, very much comes from the discipline that the use of a structured approach can bring to the process.

The initial phase involves a defined period being set aside to pin down what the key challenges and objectives are, and what the overall framework should be. Only submissions that directly concern these framing matters will be accepted at this stage, which begins with a consultation by the regulator, and ends with a decision on a range of framework matters. That decision closes the first phase of the review. While this closure is not necessarily absolute, there would need to be a compelling reason to revisit it, and even then the extent of revisiting is likely to be kept to a minimum.

A benefit of having this clearly demarcated initial phase is that it can allow for

[29] This section is based on a note by Tim Keyworth of the Regulatory Policy Institute (RPI)

[30] The processes in telecoms and in relation to airports include legal requirements for market power assessments to be undertaken, and this affects their overall structure to some extent.

Table 2: Indicative overview of a price control process

Key steps	What matters are addressed by the regulator?
Determine the overall framework/strategy	• Specify what the key challenges and objectives are for the control period • Determine what the overall form and scope of the control should be • Set out in broad terms how company submissions will be assessed • Identify the types of incentive schemes and 'uncertainty mechanisms' that may be applied
Determine the methodology	• Determine the set of methodologies to be used to assess parameter values • Determine how the application of incentive schemes and uncertainty mechanisms will be assessed.
Initial proposals	• Set out an initial view of the appropriate package of arrangements (with details of how it fits with the determined framework and methodology) • Provide an assessment of how it is expected to deliver the desired outcomes, and of the risks associated with that.
Final proposals	• Set out the final position that is to be implemented. • Detail the challenges and concerns raised in response to the initial proposals, and how they have been assessed and (where relevant) taken into account.

much more constructive engagement than might be expected later in the process (when different policy choices can be expected to have more obvious and direct consequences). This can facilitate more willingness to invest more positively in the development of the overall framework, in a context where coherent framework development is often far from straightforward.

Taking a reasonable amount of time to examine framework questions up-front can also have the effect of improving the nature of the debate in later stages, as it can provide for more of a settled and structured basis for engagement. For example, later stage engagement is likely to be much more persuasive where it can be shown to link back to and reflect considerations that were clearly articulated at the framework stage. This can lessen the likelihood of arbitrary and/or surprising decisions being made, because such decisions would imply a break from the framework that had been settled upon. Regulators often seek to try to reinforce this by using their reputation – e.g. through stated commitments - to try to provide greater confidence that the framework that has been settled will indeed be applied later on.[31]

[31] Ofgem's RIIO Handbook can be understood, in part, in this context, as departing from the Handbook without very good reason would be expected to result in reputational damage: Ofgem (2010) Handbook for implementing the RIIO model.

6.2 The form of the control

This kind of price control process specification can be particularly helpful when considering the form of control questions. A standard regulatory approach that has been developed to address the form of control questions is to break it down into a number of components. In particular, the approach can be understood as having three parts:

1. **A 'base' form of control:** this is the primary mechanism through which the price control works;
2. **Specific inventive schemes**: these are defined separately from the base control, but are set in such a way that particularly types of performance can be rewarded (or penalised); and
3. **Uncertainty mechanisms**: these are mechanisms that are explicitly intended to manage a number of different risks (for example, how the recovery of more or less revenue should be handled).

One notable feature of this modular approach to setting the control is that it explicitly allows for different parts of the control to be targeted at addressing different risk management issues. This inevitably means that coherence checks become a very important part of the later stages of price control process, but is also means that the form of control question can be broken down into more manageable packages in what can be very helpful ways.

In process terms, this can mean that the position on the base form of the control can be decided at the end of the initial phase, but the need for additional incentive schemes and uncertainty mechanisms can also be recognised at that stage, by reference to the objectives and challenges that have been identified. The form of these incentive and uncertainty mechanisms need not be pinned down at the end of the first stage (as this concerns 'fine tuning' of the mechanics), but the types of mechanism that under consideration could be settled at that stage. Then, attention in phase 2 should shift to assessing the case for different approaches to these mechanisms.

A simplified illustration of this from an energy context could be something like the following:

1. **Base form of control:** maximum total allowed revenue.
2. **Incentive scheme:** extent of interruptions as compared with target level can result in the maximum total allowed revenue being increased or decreased.

3. **Uncertainty mechanisms:** maximum total allowed revenue adjusted each year on the basis a debt cost index. Also, a defined mechanism for addressing differences between actual revenues and the maximum total allowed amount.

6.3 Relevance to the PPRS negotiations

Given the scale of the financial consequences that can be associated with differences in the outcome of price control determinations it is unsurprising that engagement between the parties can become highly contentious.

Specifying key challenges and objectives can be a particularly important part of the initial phase. It can provide an opportunity to explicitly recognise and document the set of relevant risks that the agreement has to contend with. For the PPRS this phase could cover the objectives of the scheme, and then under each objective, the issues to be addressed in discussion. It would need to recognise the concerns of both parties. The purpose would be to provide focus, rather than a "laundry list" of longstanding issues between the parties.

In terms of the form of price/expenditure control, one could potentially envisage a set of available mechanisms being reviewed within such a framework. Likewise, a discussion around NICE and an affordability cap and process involving NHSE, or revisiting flexible pricing, or something more fundamental about NICE reform, could be discussed within an agreed framework of options.

The next stage would be to reach agreement on the preferred option(s) to achieve each of the objectives, setting out how they would enable the objectives to be met. Here, the issue is that the negotiation will involve trade-offs, unlike the utility regulatory process.

It is important to note that utility regulatory price control processes are typically lengthy: Ofgem and Ofwat's processes are typically around 2-2.5 years (and can involve discussion documents that pre-date the initial framework phase). In practice, though, a significant portion of this time burden is driven by the company specific business plan submission and assessment processes, which are not directly relevant in a pharmaceutical context. A variation of the broad framework set out in Table 1 might provide a basis for structuring a PPRS negotiation process in a productive way.

7 Review and analysis of alternative options

The PPRS needs to be a comprehensive agreement between government and industry on a range of issues, meeting the coverage and efficiency objectives set out in Section 3.

In this section we do not address life sciences strategy issues. We also do not consider an alteration to the current five year length of agreements, which has been the norm in utility regulation, as in PPRS agreements, and reflects a reasonable balance between (i) stability; (ii) the need to avoid constant renegotiation; and (iii) recognition that circumstances change over time in ways that were not anticipated requiring new solutions. We focus on options in relation to the overall expenditure/affordability framework, in the light of the analysis we have set out. These are:

1. Some form of less regulated environment involving more direct negotiation with NHSE and the other three nations, with an assumption of competition operating in many market segments.
2. Separation of the arrangements for new products from those for established products. The use of an RPI-X control for established products, with NICE providing an indirect price control (via the threshold) for new products.
3. The continuation of an Aggregate Revenue Growth Rate Cap, with a focus on how to improve uptake of medicines under such a control.
4. A move back to a price cut and return on capital profit control PPRS.
5. Use of an incentives based control, drawing on the RIIO (Revenue using Incentives to deliver Innovation and Outputs) approach used in utility regulation. It seeks to re-create the incentives unregulated companies face in the market.
6. An integrated NICE/NHSE flexible pricing and affordability approach. This could be regarded as complementary to option 2.

All of the options assume free pricing, i.e. the company sets the list price for new products. We consider in each option the potential for reducing any duplication of regulatory instruments, and a general reduction in the burden of regulation on both DH and the NHS, and the industry.

7.1 A less regulated environment involving direct negotiation

This option is equivalent to the essentially deregulated US solution. As we noted, the case for regulation is not on the supply side, which is competitive, but due to third party payers facing pressure from patients, and clinician insensitivity to

price. If payers have bargaining power, then they can counteract this effect in negotiation. As we noted earlier, if there are competing suppliers then tendering is more likely to be effective in reducing prices. If competition is limited, payers will only have bargaining power if they have to have the ability to say "no" to clinicians and patients. When groups of doctors with prescribing powers are cash-limited, this provides an alternative mechanism to restrict the growth of the drugs budget, although the impact may be on volume rather than on price. It shifts the focus of regulation to the setting of the drug budget caps rather than prices.

Negotiation may well focus on the most innovative products, as seems to be happening in England at the moment with the introduction of budget caps on new products triggering negotiation with NHS England. There is always a risk that the bargaining power of the payer pushes prices below those that provide a return on R&D. We assume in this environment that NICE's TA role would either be abolished or be an advisory first stage of advice to NHSE before the second stage of NHSE negotiation with the company.

A characteristic of the US free price environment is regular increases in prices. This is unlikely to be politically acceptable to a UK government and would lead to demands for the use of the Government's Statutory Scheme price control powers. Industry could argue that the CMA would be there as a backstop to ensure there was no anti-competitive behaviour or abuse of market power. However, DH regard the CMA as an ineffective deterrent which punishes transgressions many years after the event. It does not see it as a substitute for direct action by DH.

It seems on balance that an environment in which there is no overall PPRS price, profit, or expenditure control but a reliance on bargaining and cash limits may well lead to arbitrary and ad hoc bargaining processes and differential access. There may well be an anti-innovation consequence as a result. The DH would retain the Statutory Scheme and would be likely to use it if direct negotiation was not deemed to be constraining medicines expenditure.

7.2 The use of an RPI-X control for established products and NICE review for new products

RPI-X remains the regulatory instrument of choice for regulators in other UK sectors as we have discussed above. Companies face a cap on prices/revenues, and firms need to ensure that the weighted average of their price/revenue increase each year does not exceed the percentage increase in the Retail Price Index (RPI) less a factor X.

The factor X represents the efficiency gains the regulator presumes the firm can reach in the regulated period. This factor can vary from company to company and be reset at each regulatory review. It can either be positive or negative (allowing prices to increase above RPI). Arguably, the longstanding PPRS price freeze with modulation on products once launched, is a form of RPI-X where X is set equal to the RPI, i.e. RPI-RPI equals a price freeze. Modulation means companies can change prices provided a volume adjusted basked shows that overall the RPI-RPI target has been met, i.e. no increase in average revenue.

A high X factor will give incentives to a company to 'avoid the control biting'. In the UK, the price freeze on medicines has led to companies selling older products to smaller companies who are outside the terms of the PPRS price control. Where this has led to price increases, the DH has expressed concern, although this is in part a consequence of its regulatory system. The price freeze does not reflect the potential for efficiency improvement. There is an implicit bargain that revenue from new products covers reduced revenues on older products. Particular problems arise however if companies are losing money, i.e. price is below manufacturing and distribution cost. An alternative to formally setting up and managing an RPI-X basket control could be a continuation of the current price freeze with modulation, plus some backstop control that allowed companies to apply for price increases when price was below manufacturing and distribution cost. However, this would need to be organised in a way that did not lead to substantial investment of effort on the part of companies and the DH respectively.

RPI-X price regulation cannot be used to set the prices of new products. It could be argued that England has a de facto hybrid scheme with NICE constraining indirectly the prices of new products through its cost-effectiveness threshold, with the price control on existing products constraining the rest of the market. The adoption of hybrid approaches of this kind is not uncommon in regulated sectors (see Section 6.5 for the telecommunication sector example). The only gap is new products that do not get assessed by NICE. Some mechanism would be needed for agreeing the prices of these products.

However, such a system would not deal with affordability/procurement issues. It could be argued that the price freeze plus local drug budgets will provide a constraint for established products. The RPI-X approach can begin with a price cut, resetting the starting prices, as we have seen in each PPRS prior to the current one. In the case of new products, an integrated NICE/NHSE flexible pricing and affordability approach could be used. We discuss this option under 8.6 below.

7.3 An Aggregate Revenue Growth Rate Cap

The current PPRS has an aggregate revenue growth rate cap. The National Grid had a revenue cap for a while, which was easier to justify for a largely fixed infrastructure business. The case for the aggregate revenue growth rate cap for medicines is the procurement challenge faced by the Government in a time of public sector austerity. The key factors to consider include how to determine the growth rate, risk issues, rebates, etc. We explain some of these considerations below.

In principle, about how to determine the growth rate, if new cost-effective medicines are introduced then money should be switched from elsewhere in the NHS to increase spending on drugs. From a budgetary control point of view, the NHS would like to know what a key component of cost will be over a five year period, and to know that it is a manageable growth rate. But the target growth rate does need to take some account of innovation and factors driving volume. Wanting certainty as to what is paid, and wanting to pay less, are not the same thing.

Any fixed growth rate passes the risk to the industry. If there is a lot of innovation then rebates will increase and companies who do not have new products may find that not only are sales flat, but that they are paying a substantial levy such that their turnover is falling. It will be important to manage incentives by keeping NICE assessment and, perhaps, some elements of competitive procurement to ensure that the returns to innovation are not excessive, as they are, in effect, being borne by the industry as a whole.

Rebate payments will be affected by this revenue growth rate, so a certain degree of predictability is expected. The formula in the current scheme has managed to do this, although the treatment of the rebates by the DH has caused complications for the NHS. There is quite a lot of regulatory experience with options for dealing with this kind of under/over recovery issue. There are also smoothing options, typically treated within the context of 'uncertainty mechanisms': i.e. mechanisms that sit on top of the base arrangements to manage particular kinds of deviation from assumed levels. Of course, the more complicated the arrangements become the harder it may become for companies to understand their likely repayments. There is a trade-off. Some sort of "cap and collar" arrangement was discussed for the last PPRS and has been agreed for the 2018 rebate, so this can be done.

Finally, if their budgets are not compensated for local overspend, but only for the average national overspend, the budget holder level (prescriber and/or purchaser) will not change given then they will not change their behaviour in terms of seeking to stay within their budgets – albeit with some estimation of potential average overspend. There are also timing issues if lags between overspend and receipt of

rebates cross an NHS financial year end. The difficulty in creating a situation in which local commissioners know that they do not need to worry if they exceed the national target is that other commissioners may underspend, so no rebate may be paid at the national level. The detailed rules agreed will be important.

So, there are trade-offs. The cap could be seen as both providing important reassurance to the DH and also as very pro-innovation, in that there is in principle nothing to stop the NHS using new medicines. Overspend will lead to rebates.

A PPRS expenditure cap could be seen as reducing the need for subsequent NHS bargaining and tendering or "double dipping", i.e. a duplication of the use of regulatory instruments to achieve the same objective. However, some constraints will be needed in the interests of both the NHS and the industry to ensure the returns to innovation are not too high. From the industry's point of view the concern will be, given that the rest of industry will be paying for them innovation in the form of a higher rebate. It maybe that NICE's cost-effectiveness threshold will provide sufficient reassurance to both parties.

7.4 Price Cut and Return on Capital (ROC) PPRS

Rate-of-return regulation has gone out of fashion in the UK in favour of RPI-X. This is primarily because rate-of-return regulation provides limited incentives to improve efficiency and cut prices, and high incentives to invest in capital to raise the "rate base" to which the profit rate will be applied. This effect is well-known as the 'Averch-Johnson effect' (Averch and Johnson, 1962), although these predictions only hold under restrictive assumptions (Joskow, 2005). RPI-X when reset, however, needs to have reference to rates of return. The regulator does not want the business to earn excessive profits, but it has to be able to attract capital for investment and remain in business. If efficiency improvements achieved are clawed back by the regulator when the new cap is set, then incentives to reduce costs are diminished.

In the context of the PPRS, the ROC/ROS element of the scheme has become less important. The concerns expressed by the OFT in its 2007 Report on the PPRS were less about the implications for efficiency, and more about the problems of ensuring an appropriate allocation of costs, notably in the transfer price for intermediate or final products imported into the UK from subsidiaries elsewhere in the world. However, if the DH is receiving information from a large number of companies it can use a variant of "yardstick competition" to disallow what appear to be excessive costs allocated to the UK business. Given (i) there is a price freeze on established products, and (ii) limited patent life means the key to industry success is successful R&D investment, which does not appear in the "rate base" , i.e. it is not capitalised,

then the concerns of most economists about ROCE control do not seem to apply to its use in the pharmaceutical sector. Appropriate allocation of global costs remains the outstanding difficult issue.

There are a number of issues with this option, though. First, the setting of the reasonable rate of return. This has historically been done by reference to the accounting returns of the Financial Times Stock Exchange 100 (FTSE 100)[32] companies in other sectors. This differs from the approach in the utilities which usually use a variant of the CAPM to estimate the underlying risk adjusted cost of capital of the business. Second, there is a case for saying that the price freeze on existing products can push companies into low profit/loss making positions. The ability to allow price rises (a relaxation of the price freeze) in response to a low return on capital would be an obvious regulatory solution. This is allowed in principle under the ROCE rules, but it is not clear whether it works in practice. Finally, whether the ability of the industry to show that it is earning reasonable rather than excessive returns from the NHS is an important message. The media typically focus on global accounting profits and rates of return, but there must be an expectation that profit rates are likely to be higher in the US than the UK and thus global profit rates are not the same as UK profit rates.

The redundancy of the profit control under the current PPRS, plus BREXIT meaning that will no longer be important to have a return on capital scheme to meet certain terms of the EU Transparency Directive, suggest that the ROC element of the PPRS could be dropped. Thought will need to be given to whether it should remain part of the regulatory picture. It could in principle, if global cost allocations were credible, provide an important reassurance to the NHS and public opinion, particularly if the expenditure control was dropped. Once abolished, it is hard to see how the ROC control could be reintroduced.

The use of a price cut instead of an expenditure control replaces a five year control with a one-off effect. The risk on expenditure passes back from the industry to the DH and the NHS. Inevitably the DH would demand a large price cut in anticipation of this. Price cuts also have international repercussions. These are not easy trade-offs for either party.

[32]The Financial Times Stock Exchange 100 Index, also called the FTSE 100 is a share index of the 100 companies by capital value, listed on the London Stock Exchange with the highest market capitalisation.

7.5 Use of an Incentives based control to deliver Outcomes

As we noted above, Ofgem proposed a new regulatory model called RIIO (Revenue using Incentives to deliver Innovation and Outputs). It seeks to re-create the incentives unregulated companies face in a competitive market without government as regulator of purchaser.

For some policy objectives, is not easy to define appropriate high-level primary outputs. In these cases, the RIIO framework allows for the use of "secondary deliverables". For example, building a specified system of car charging points might be the secondary deliverable that facilitates the primary output of increased electric car usage.

This type of regulation, more widely known as performance-based regulation (PBR), is being discussed for the future of pharmaceutical manufacturing quality in the US, more specifically as monitored by the US Food and Drug Administration (FDA). The idea is that pharmaceutical regulation should be designed to improve the performance of individual and organisational behaviour in ways that protect and promote public health. PBR actions focus on identifying performance measures that ensure an adequate safety margin and offer incentives for companies to improve safety without formal regulatory intervention by the agency.

It might be possible in principle to have an RIIO arrangement within a PPRS that sought to link, for example, allowable expenditure to the health outcomes achieved. This kind of approach would provide for 'base' expenditure, but then would also allow for outcome related rewards and/or penalties over and above this base. Typically, these arrangements could be introduced in a relatively low-powered way (i.e. the rewards were not large) while confidence is gained in terms of information gathering and the reasonableness of the targets. They could then be ramped up where appropriate at a review point in the PPRS, or in a subsequent scheme.

8 Conclusions

The purpose of this report was to review the current economic regulations of the UK pharmaceutical industry, study the regulations of the other selected OECD countries, and explore the experience of the UK's public utility sector in economic regulations. We reviewed the options for future regulations in the UK pharmaceutical industry and listed options that seem worth considering.

There are several reasons why studying UK regulation on drug pricing is challenging. First, the reasons for regulating the pharmaceutical industry are quite distinct

from other regulated sectors, such as water, gas, and electricity that are characterized as being natural monopolies. The pharmaceutical industry is not an intrinsic natural monopoly. Second, drug pricing regulation is not without a cost. The pharmaceutical industry is one of the few UK high-technology industries manufacturing high value-added products that have succeeded in competing in the international market, which has positioned the UK as the seventh-largest pharmaceutical market globally. Any measure affecting incentives to innovate in this industry will affect the strategic position of the UK worldwide. Third, because the current price regulation regime in place in the UK is complex and unique in the world, and the effects of new measures that are easy to forecast in other settings, are not obvious in the PPRS environment.

The critical research we have made of regulatory regimes in relevant countries and other regulated sectors inside the UK has given us important lessons. On the one hand, the PPRS is a complex regime with many drawbacks that are not easy to tackle. Nevertheless, it allowed the UK to develop and sustain a strong industry while keeping the NHS's costs low compared to other comparable countries. On the other hand, from other sectors, we learned that whatever regulation regime must be designed to encourage competition; improve outcomes for customers/patients; while keeping prices down in a way that is compatible with companies earning a reasonable return encouraging product innovation.

The budget cap in the last PPRS comes from an urgent need to reduce the UK's burden of health expenditure. With this aim, we think there is a need to regularise the arrangements for NHSE to get involved in the NICE decision-making process. Irrespective of the level of budget impact chosen, the NHSE involvement needs to be structured so that it is not sequential and so delays access for new drugs. Arguably NICE needs to manage this as part of its process.

All in all, we can say that although there are other available alternatives to the current system that seems attractive, further economic analysis is needed to measure the costs and benefits of these options.

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A Rationale for regulating utilites

Most regulated industries are in the utility sector, such as gas, water, airports, electricity and telecommunications. All of them share a common characteristic: they all exhibit significant market power problems, often as a result of the natural monopoly characteristics of some parts of the infrastructure they use to supply their customers.

A natural monopoly is a type of monopoly that exists as a result of high fixed cost and low marginal cost of production that makes the cost function exhibit classic economies of scale, i.e. falling average cost of production as the total quantity increase. In other words, the minimum efficient scale[33] is not reached until the firm has become very large in relation to the total size of the market. The industry could serve the entire market at a lower cost with one single firm than with multiple firms.

In competitive markets, demand is large relative to the extent of any economies of scale, so there is no conflict between achieving cost minimization, at the industry level, and limiting market power by having a large number of firms. In a perfectly competitive market, firms' price equal to the marginal cost (allocative efficiency) at

[33] A minimum efficient scale is the lowest level of output at which a firm achieves the economies of scale required to operate efficiently and competitively in an industry.

the minimum of their long-run average total cost function (productive efficiency). In the case of a natural monopoly, cost efficiency requires production by a single firm, but allocative efficiency requires many competitors to eliminate market power. Market forces alone do not bring the socially desirable outcome and economic regulation is required.

In the monopoly parts of the utility sectors, a new company wanting to enter the market is likely to have to duplicate the infrastructure to be able to provide the service (pipelines, power transmission and distribution towers, airports, sewer system and wastewater treatment plant, etc.); this implies duplication of fixed costs. It might not be possible for the second firm to access the market at a lower average cost than the incumbent.

Economic regulation in the utility sector typically focusses on:

(i) the potential for introducing or increasing competition, notwithstanding the natural monopoly challenge, for example by introducing new technology which bypasses existing infrastructure, or by requiring companies to "rent out" parts of their infrastructure to competitors on fair terms;

(ii) price control or revenue control to protect consumers whilst also providing a strong incentive for companies to improve their efficiency, and so their profits;

(iii) the potential for measuring the quality of the output delivered to customers including aspects of customer service;

(iv) providing incentives for major new investment – perhaps linked to the introduction of new technology that provides new services or much improved quality.

(v) managing the trade-offs between the four objectives (i)-(iv) above.

B International experience

Germany

This section is based on Lauterbach et al. (2016); Gissel (2013); Paris and Docteur (2008).

The German market is characterised by the absence of direct regulation of ex-factory prices, even for reimbursed products (but they regulate distribution margins and retail price). Historically, as with the U.S., Germany has had a reputation for high drug prices. Then, after the introduction of the 2011 Pharmaceutical Market Reorganization Act (AMNOG) they started negotiating prices of new drugs based on benefit assessments rather than cost-effectiveness analysis (CEA). In 2015 alone, Germany achieved savings of $ 1 billion on new drug spending, with discounts averaging 21 percent in this market segment.

The Statutory Health Insurance (SHI) sickness funds are the most important payers in the German health care system. They are represented by the National Association of SHI Funds that is in charge of negotiating rebates agreements with the pharmaceutical manufacturers. The German legal system requires all citizens to seek health insurance either by the SHI funds or by private insurers.

The Federal Joint Committee (Gemeinsamer Bundesausschuss, GBA) is the most important self-governing body in the German health system, and commissions the early benefit assessments of new drugs to the German Institute for Quality and Efficiency in Health Care (IQWIG). The IQWIG is an independent scientific institute for pharmacoeconomic analysis, usually reporting to GBA. Finally, the German Federal Ministry of Health has legal supervision over GBA but not functional supervision, which means that can only void GBA's actions if deemed unlawful.

The AMNOG Regulation works as follows (Lauterbach et al., 2016). First, once a new drug has been demonstrated as safe and efficacious by the European Medicines Agency (EMA) or by the German Federal Institute for Drugs & Medical Devices, the drug maker may introduce the product into the German market at any initial price of its choosing, fully reimbursed by all German insurance plans for the first 12 months, until the drug is subject to reference pricing or a rebate agreement (Germany adopted reference pricing in 1989).

During those 12 months, the GBA commissions IQWIG with an early benefit assessment based on a dossier the company submits to GBA. Results are subject to an expert hearing published and used to inform both doctors and patients. Based on that report, the GBA determines the new drug's added benefit over existing drugs or treatments, including information on benefits and risks for specific patient subpopulations.

If the GBA accepts the new drug is found to offer additional benefits, the drug price is negotiated between the manufacturer and the National Association of SHI Funds. If parties cannot reach agreement, the matter is submitted to an arbitration panel for a decision based on other international prices. If a drug offers no additional value over a previously available drug, the drug is allocated to a reference pricing group. Payers will reimburse only at prices currently paid for the older existing drugs or therapies. Drug companies can choose to sell their product at higher prices, though patients who want the newer and lower ranked drug must pay the difference out of their own pockets.[34]

A drug company can opt for their drug to not be assessed, in which case the

[34] Importantly, if a drug company charged an excessive rate for a lower ranked drug in the first year of availability, the extra revenues must be returned to payers.

drug's price is set through the German reference pricing system. Under the reference pricing system, a drug's price is based on the price of other drugs in that therapeutic class, including lower priced generic alternatives.

GBA decides for which medicinal product a reference price can be defined and forms the groups of medicinal products. In these groups medicinal products are combined based on (1) the same active ingredients (2) pharmacologically-therapeutically comparable active ingredients or (3) a therapeutically comparable action. The maximum reimbursement amount is computed for each cluster using an econometric model that takes into account the prices of existing products. Then, the National Association of SHI Funds sets the reference price for the medicinal products. The criteria for setting the reference price for a medicinal product are regulated by law. The list of reference prices for medicinal products is updated quarterly and published on the websites of German Institute of Medical Documentation and Information (DIMDI).

The Netherlands

The Health Insurance Act (*Zorgverzekeringswet*) came into force on 1 January 2006 and make it mandatory for all residents of the Netherlands to have a basic health insurance. Under this framework, all residents are entitled to the same core basket of health services, which they purchase from private health insurers, which must accept all Dutch citizens, with public social conditions. On top of the basic health insurance, residents can take out voluntary health insurance to cover additional services (Ruggeri and Nolte, 2013).

The Ministry of Health decides which new medicinal products shall be placed on the Drugs Remuneration System (Geneesmiddelen Vergoedingssysteem, GVS), which consists in a positive list of reimbursed products. The execution of the GVS is assigned to the Minister of Health which in turn consults with the Health Care Insurance Board (*College voor Zorgverzekeringen,* CVZ). The CVZ evaluates and informs about the therapeutic value, patient benefit, cost-effectiveness and financial impact on the core basket of services, but the Ministry of Health is the one that takes the final decision.

The pricing of medicinal products is regulated by the Medicinal Products Prices Act (Wet Geneesmiddelenprijzen, WGP).[35] It applies to all prescription-only medicines that are dispensed by pharmacies and dispensing doctors. Reimbursements and regulated tariffs are regulated by the Health Insurance Act and the Market Organisation Healthcare Act 2006.

[35] The pricing of medical devices in not regulated.

The WGP allows the Minister to fix maximum prices based on the average official list price of comparable medicinal products in Belgium, Germany, France, and the UK. Prices are revised every six months, taking into account changes in the prices of medicines in reference countries and fluctuations in the exchange rates. Before 2008, maximum prices only applied to outpatient drugs, but since then a small but increasing number of inpatient drugs is being covered under the Price of Drugs Act.

A maximum price is calculated if a comparable product is marketed in at least two of the four countries, and the product is eligible for reimbursement. A comparable product is a product with the same active substance, unit strength of active substance and pharmaceutical form (including generics and biosimilars). Maximum prices are calculated using set price lists for each country to determine the cheapest available "comparable" product. The average of these prices will be equal to the maximum retail price in the Netherlands. This system is used for branded and generic medicines. The existence of maximum prices does not disregard the possibility for hospitals, wholesalers and pharmacies to negotiate and get discounts.

External reference prices are applied to all outpatient drugs, including branded and generic drugs, and high-cost medicines and orphans drugs for inpatient care.

France

The French health system is based on Statutory Health Insurance (SHI) and provides all legal residents with health coverage, as per the 2000 Universal Health Coverage Act (CMU).

There are three key players involved in pricing policies in France. The Transparency Commission (*Commission de la Transparence*), a body of the French National Authority for Health (*Haute autorité de santé*, HAS), is in charge of the assessment of the medical benefit of a drug, which forms the basis for price negotiations. The Healthcare Products Pricing Committee (*Comité économique des produits de santé*, CEPS) determines the price through negotiations with the industry. The third player is the pharmaceutical industry.

Pricing strategies in France differ depending on whether the medicine is primarily used in the pharmacy market (out-patients) or the hospital market (in-patients).

In the case of outpatient care, pharmaceuticals are classified into "prescription only" (Rx) and over-the-counter (OTC). Only Rx drugs are reimbursed by the SHI and special pricing mechanisms apply.[36] The ex-factory price[37] and the pharmacy

[36] For non-reimbursed drugs, pricing is set freely.

[37] Ex-factory price refers to the cost a manufacturer charges for a distributor or other buyer to purchase products directly from the source. It does not include shipping, handling or taxes.

retail price are both regulated.

Under this procedure, the pharmaceutical company proposes a price and justifies the reasons for that price, and they negotiate it with CEPS. In the case of drugs considered as of moderate to high added therapeutic value, negotiations are based on external reference pricing. The price in France should be consistent with the prices in place in the main EU Member States. This means that the initial listing price should not be lower than the lowest price observed in Germany, Italy, Spain and the United Kingdom. The initial list price for these drugs is fixed for a period of at least five years. The use of external reference pricing was chosen to ensure a rapid access to innovative drugs (Ruggeri and Nolte, 2013). There are no maximum prices for drugs.[38]

Drugs considered as of no or low added therapeutic benefit negotiations are based on the price of the most appropriate comparator drug, and also on external reference prices. The idea is that the new drug should not lead to higher expenditures for the SHI. Negotiations between the company and CEPS results in a contract which is revised each semester and which may last up to 4 years.

Prices for generic drugs are determined by the Government based on a fixed proportion of the originator price through negotiations with the industry, and for generics with insufficient penetration into the market an internal reference pricing system applies.

Price is negotiated, based on the product's medical value, prices of comparable medicines, volume sales conditions used and omparisons with other European countries for 'innovative' products. There are also periodic price reductions for new and expensive products.

In the case of pharmaceuticals sold in the hospital market, drugs must first be admitted onto a list of drugs agreed for use in hospitals. Once included, prices are freely negotiated subject to public procurement rules (if applicable).

In the case of reimbursements, only Rx drugs may be reimbursed, and the process is not automatic. To qualify, the drug must be added to the list of reimbursed drugs and be prescribed correctly. Eligibility depends on the medical benefit (*Service Médical Rendu*, SMR): for the highest benefit, the reimbursement rate is of 65% ; if there is no improvement in the SMR, the drug cannot be reimbursed. Given that most patients have complementary voluntary health insurance policies which cover part or the whole difference between the reimbursed amount and the actual sale price, the rate of reimbursement is not an issue for companies.

[38] Nevertheless, for drugs with a high budget impact, CEPS may negotiate price discounts during these five years and after.

New Zealand

New Zealand's healthcare system is predominantly publicly financed. For many years New Zealand experienced a rise in expenditure on community drug treatment that became a major problem in the eighties. Then, in June 1993, the Pharmaceutical Management Agency (PHARMAC) was established with the aim to securing the best health outcome from drug treatment, within the amount of funding available. New Zealand does not use pharmaceutical price controls, leaving prices to be determined by negotiation. However, PHARMAC is a very effective monopsony purchaser, negotiating the prices of inpatient and outpatient medicines, vaccines and medical devices, and managing a capped national budget for outpatient and cancer pharmaceuticals.

Once a drug is approved for sale, the company can apply to PHARMAC for it to be government funded. PHARMAC's key role is not only to negotiate prices, but also decides whether a medicine will be subsidised or not, and conditions of access. The decision whether to fund is based on several criteria. However, one of the key criteria is cost-effectiveness. PHARMAC uses cost per QALY to calculate incremental costs and benefits of a new drug.

Given that PHARMAC decides on which medicines should be subsided or not, and is also in charge of negotiating prices based on a variable annual budget, there is no single cost per QALY threshold. The data is used to create a relative ranking of medicines that could be funded and they are funded according to their position in the list, along with information on other decision criteria (Cumming et al., 2010). All the funded medicines are available on the Pharmaceutical Schedule.

PHARMAC uses a variety of mechanisms to obtain lower prices, including competitive tendering, sole supply contracts, reference pricing, bundling deals, risk sharing agreements and promoting use of generics. The reference pricing is used to set government subsidies at the same level for medicines in the same therapeutic subgroup, forcing suppliers to either match the lowest price or, if the actual price is higher than the government subsidy, patients need to pay the additional cost. For medicines not available on the Pharmaceutical Schedule (nonfunded medicines), the patient has to pay "out of pocket" .

When a new product enters the market, it is only reimbursed if it joins an existing therapeutic subgroup, which requires offering a price below the prevailing reference price. The product that is not clusterable may sometime be reimbursed if PHARMAC and the manufacturer agree on a reimbursement price. The reference price is set at the lowest price in each therapeutic subgroup, regardless of patent status. Manufacturers could set a price above the reference price, but PHARMAC

may eliminate all subsidy if the product cannot show to provide additional clinical benefit than a substitute available at a lower price.

Alternatively, cross-therapeutic deals are possible. This is a situation where a manufacturer of a new product offers to reduce its price on another of its products in another therapeutic in order to be allowed to set a higher launch price in a new product.

Australia

The Australian health care system provides universal access to a comprehensive range of services, largely publicly funded through general taxation. Medicare was introduced in 1984 and covers universal access to free treatment in public hospitals and subsidies for medical services. The system is financed largely through general taxation.

Private health insurance is highly regulated. Insurance can cover private treatment in hospital (duplicating the public coverage) and out of hospital services not covered by Medicare, for which the majority of services are dental care and physiotherapy.

The Pharmaceutical Benefits Scheme (PBS) provides subsidised drugs at a set co-payment. This comprises over 90% of all prescriptions written in Australia. Patients therefore pay the set co-payment regardless of the cost of the drug they receive. There are safety net provisions in place to limit total expenditure.

The medicine will not attract an Australian Government subsidy unless the sponsor is also successful in listing the medicine on the PBS. Applications for PBS listing are considered by the Pharmaceutical Benefits Advisory Committee (PBAC), which is an independent expert body appointed by the Australian Government. The PBAC bases its decision on the cost-effectiveness or 'value for money' of the new medicine when compared to existing treatments. The PBAC uses a Health Technology Assessment (HTA) methodology to evaluate applications. Consideration of a new medicine by the PBAC can result in one of three outcomes: i) a recommendation to Government that the medicine be listed on the PBS, ii) a decision not to recommend listing on the PBS, or iii) the deferral of a decision pending additional information. If a positive recommendation is given by the PBAC, the sponsor must still negotiate the final arrangements for listing on the PBS, including pricing with the DH. Final approval can be granted by the Minister for Health, unless the net cost of the medicine to the PBS is more than $20 million per year, in which case Cabinet approval is required for PBS listing.

There exist two representative bodies of the pharmaceutical industry. Medicines

Australia (MA) represents the innovative (patented) medicines industry, and the Generic and Biosimilar Medicines Association (GMBA) represents generic and biosimilar (off patent) medicine suppliers in Australia. In 2015, GMBA signed its first Strategic Agreement with the Government, containing measures to promote the increased usage of cheaper generic and biosimilar medicines on the PBS. The Strategic Agreement acknowledges that such medicines increase price competition leading to significant savings for the Government.

Price negotiations with the responsible person for new or changed listings are undertaken by the Pricing Section on behalf of the Minister, following a positive PBAC recommendation. There are four possible pricing methods to be used:

1. Cost plus method. The cost plus method is most commonly used in the case of stand-alone products, those recommended on the basis of acceptable cost-effectiveness and where no specific relativity exists, or when recommending a benchmark price for a therapeutic group. The cost plus method relies on the manufacturer information, who should provide the detailed information.

2. Reference pricing. Reference pricing is set according to the principle of cost-minimisation. The lowest priced brand or drug sets a benchmark price for either the other brands of that drug or the other drugs within the same subgroup of therapeutically related drugs.

3. Pricing of new strengths of existing items. For new strengths of already listed drugs, as a general rule, the pricing of half strength formulations is at two-thirds to 70% of the full strength.

4. Weighted Pricing. For a small number of drugs with multiple indications, each indication may have an indication-specific price which relates to its cost-effectiveness for the eligible patient population. This generally involves applying a weighting to each indication-specific price and then adding these prices together in order to arrive at a single weighted price. These weightings are generally based on Medicare Australia data for the particular indication over a dispensing period.

Drugs covered by the PBS are listed in two formularies: i) formulary one (F1) consists of drugs which have only one brand each; and ii) formulary two (F2) consists of drugs which have two or more brands each. Drugs on F1 move to F2 when the first additional brand is listed on the PBS.

The PBS expenditure is not capped in Australia. However, pharmaceutical prices can be reduced. The reform of 2015 established several changes in the PBS pricing.

It focused on price reductions for multiple brand (F2) medicines, but it also focused on a statutory price reduction for single brand innovative (F1) medicines. The Government argued that F1 medicines were the fastest growing part of the PBS by cost, and that it was reasonable for these medicines to take a small price reduction after five years on the PBS, in order to support the listing of new F1 medicines. If an F1 drug is listed on the PBS for more than five years, a five percent reduction is applied in the approved ex-manufacturer price (AEMP). Each drug will only take the five per cent reduction once.