



Tender Loving Care?

Purchasing medicines for continuing therapeutic improvement and better health outcomes

Summary

- Medicines and allied products, including vaccines and diagnostics, will cost the English NHS £16 billion this year (2016 gross figure, NHS discounts not deducted). They account for up to 13 per cent of total health service spending, or about 1 per cent of GDP. Expenditures on this scale require careful control. However, overall medicines outlays are as a percentage of national income below the OECD average. NHS prices are for many treatments lower than those accepted in countries such as France and Germany.
- Pharmaceutical advances, including improved use of existing products as well as new treatments, are estimated to have been responsible for around half of the 15 year gain in life expectancy at birth seen UK wide since the creation of the NHS in 1948. They will in future generate further gains in areas such as oncology and neurology and the treatment of rare diseases. The British public has important interests in both assuring the affordability of pharmaceutical products and encouraging further industrial investment in pharmaceutical research, development, production and supply.
- The Pharmaceutical Price Regulation Scheme (PPRS) and NICE play important roles in limiting both the prices paid for individual medicines and the overall costs of pharmaceuticals in England. Since the 1950s the NHS has also built up world-class expertise in the purchasing of both generic and branded medicines for hospital use through tendering based processes. Such procurement skills are important in supporting specialised care provision as well as day-to-day care. In the case of branded products Multi-provider Framework Agreements can when working well allow local clinicians and patients to choose treatments appropriate for their needs while containing nationwide costs.
- UK law relating to the public procurement of items such as medicines is based on a relatively new (2014) EU Directive. It is unlikely to change in the foreseeable future. Since public spending on purchasing goods and services from private suppliers accounts for about 15 per cent of all economic activity in countries like the UK it is vital to obtain optimum value for money while stimulating ongoing innovation. Both the European Commission and HM Treasury emphasise that simply minimising purchase prices does not guarantee best value.
- Identifying the ‘Most Economically Advantageous Tenders’ (MEATs) on offer involves assessing the ‘whole life’ value of competing bids, and exploring all aspects of the value that can be generated by constructive partnerships between producers like research based pharmaceutical companies and the users of their products. People with unmet therapeutic needs can gain both from fundamental scientific progress and from developments in the ways that established treatments are used to optimise individual health outcomes.
- During tendering processes weightings can be applied to each quality criterion to identify ‘best buys’. However, this can in practice be difficult to achieve in a manner acceptable to all the stakeholders involved. Significant legal constraints may also apply. Consequently, the forces favouring ‘lowest price’ as against ‘optimum value’ purchasing are often hard to overcome. Achieving due sensitivity to both personal needs and wider community interests demands a robust balance between serving patient and public interest focused professional concerns on the one hand and the pursuit of financial savings on the other.

- The bleeding disorders known as haemophilia are today treated with replacement blood Factors produced by recombinant bio-engineering technologies. This field offers an example of one in which the use of tendering systems to purchase medicines is estimated to have cut costs by around a third in about 10 years without undermining access to medicines. However, the contributions of pharmaceutical companies to improving outcomes through initiatives such as funding outcome data bases and specialist nurses should be recognised in contracting processes. There is evidence that outcomes for people living with haemophilia could be further improved by more personalised care.
- Despite controversies regarding the provision of ‘cutting edge’ cancer treatments to NHS patients and the UK’s historically poor record in overall research funding compared with nations like South Korea, the US, Germany and France, this country’s performance with regard to pharmaceutical research and care has to date been relatively good. However, future failures to achieve well balanced medicine procurement and linked commissioning and care strategies could undermine partnerships between pharmaceutical companies and NHS organisations like specialist care centres. This might impede health service improvements and harm the economy.
- In the period leading up to Britain’s withdrawal from the European Union the health service may, along with other public services, have to face new pressures associated with reduced national earnings and falling tax receipts. There is a danger that this will cause NHS hospital/specialised medicines procurement, which since the troubled NHS reforms has become more directly influenced by NHS England, to be focused on cutting immediate costs rather than seeking maximum patient and community benefits. At worst, this could alienate NHS users and clinicians, whose cooperation is vital for allowing Multi-supplier Framework Agreements for obtaining branded medicines to function well.
- Inadequate procurement approaches might also threaten the sustainable supply of some medicines and further undermine the UK science base. Some commentators fear that the latter is already at risk of being damaged by the medium to long term consequences of ‘Brexit’.

Recommendations

- Policy makers in England and the other UK countries should seek to ensure that the strategic thinking underlying the MEAT approach outlined in the revised 2014 European (Public) Procurement Directive is made central to the tendering methods and decision making employed in the NHS. Otherwise the system that will evolve could, contrary to the underlying aims of NICE and the UK Pharmaceutical Price Regulation Scheme, come to focus exclusively on minimising the purchase prices of treatments at the expense of quality and ongoing product and service innovation.
- Explicit mechanisms should be in place to preserve a good balance between promoting medicines affordability and incentivising innovation. One step towards this could involve creating a system for research based pharmaceutical companies to have their performance as ‘NHS Innovation Partners’ evaluated and recognised by an independent body. Once awarded, such rankings could – with other relevant variables – be used to help weight MEAT procurement decisions in order to prevent them being ‘swamped’ by price minimisation pressures.
- Without appropriate safeguards to limit the counter-productive use of monopsony (single purchaser) powers it may become increasingly difficult to deliver the twin goals of preserving a high quality health care system and ensuring that this country provides an attractive setting for researching, developing and providing better pharmaceutical treatments. In the final analysis the health service must keep within its allocated budget. But the ultimate purpose of the NHS is to help make sure that Britain enjoys an equitable and prosperous society, and that that individuals affected by illness receive the best care that it is possible for the community to offer to citizens who are disadvantaged by potentially disabling and life threatening diseases.

Introduction

April 17th 2016 was World Haemophilia Day. It was also the day that it became mandatory for European Union Member States to adopt the provisions of a new Directive on Procurement (2014/24/EU) by public bodies into their national legal frameworks. Its terms and requirements replaced those set out in an earlier 2004 Directive. They seek to remove unnecessary bureaucracy and improve the efficiency and effectiveness of the purchasing of goods and services undertaken by publicly funded bodies, while also curbing tendencies to undermine community-wide interests by minimising the prices of items at the expense of quality and ongoing innovation.

At first sight European public sector procurement policy might not seem like a topic that should be of any great interest to doctors, political leaders or the members of other groups whose main concerns centre on protecting patient and public health in the UK, especially now that the country has voted to leave the EU. Yet in reality it has important implications for the future of not only Europe's economy but also that of Britain in an era of increasing challenge, both social and financial. More narrowly, procurement policies have potentially important impacts on the development and appropriate supply of not only established 'generic' (off-patent, unbranded) medicines but also newer treatments that can prevent, alleviate or cure non-communicable 'genetic' conditions like cancers or rarer disorders such as haemophilia, or those transmissible infections that still threaten humanity. Examples of the latter include AIDS and Hepatitis C.

The Pharmaceutical Price Regulation Scheme (PPRS) has for decades played an important part in limiting the overall costs of NHS medicines and allied pharmaceutical products. Since the end of the 1990s the National Institute for Health and Care Excellence (NICE) has – in England and Wales – also been very visibly involved in judging the extent to which selected new treatments are sufficiently cost effective for NHS use. It currently has a pivotal role in defining the therapeutic entitlements of NHS users seeking care that meets their needs.

However, over and above the work of the PPRS and NICE and its Scottish counterpart, The Scottish Medicines Consortium (SMC), procuring both generic and branded medicines demands direct purchasing skills. This is particularly so in hospital and other specialist care contexts, including those in which the volume of pharmaceuticals used is comparatively small but the unit costs of alternative products tend to be high. In such instances pharmaceutical procurement is likely to involve tendering processes and the issuing of contracts for the supply of treatments that meet individual needs in a way that is affordable for the NHS as a whole, given the finite resources available.

Identifying what are genuinely the best value (or in the language of the 2014 Procurement Directive, the '*Most Economically Advantageous Tender*' – MEAT) offers from companies that not only manufacture sophisticated products such as 'biological' medicines to a high standard but in addition seek to provide them in ways that help improve health outcomes, can be a difficult task. High quality medicines procurement goes beyond simply seeking to minimise the unit prices paid. In the health arena successful strategies should also aim to ensure that adequate production capacity is maintained in the medium to long term and that financial savings are not obtained at the cost of undermining appropriate forms of clinical freedom and patient choice. Avoiding needless costs is obviously important. Yet unduly low prices tend to drive out competition and create shortages.

Constructive co-operation between producers and the users of goods like pharmaceuticals is also to be encouraged. This requires purchasers to be sensible of the commercial realities affecting organisations such as privately (and publicly) owned companies. No independent firm can over sustained periods produce good quality items and invest in research and development without making profits sufficient to attract ongoing capital investment. Yet at the same time all successful health sector enterprises need to make the promotion of patient and wider community wellbeing their central goal. This means that companies selling to the NHS need to act with insight and restraint when health care providers are facing rising demands but stable or falling funding.

Against this background, the objective of this brief report is to provide an overview of the changing system for purchasing NHS medicines and allied products in England, and the parts to be played in obtaining good value for money by not only health professionals such as pharmacists and doctors but experts in procurement working as positively as possible with partners in industry and patient organisations. It explores why price alone is often only a partial guide to value. Relevant concerns range from variations in the pharmaceutical and/or pharmacological properties of alternative treatments and the benefits they offer individuals through to the extent to which competing companies invest in clinical care improvement and patient support programmes.

Balancing price and value

The analysis offered starts with a brief overview of the strategic drivers of procurement policy and the systems in place for purchasing hospital medicines, including specialist treatments, and limiting their costs in England. It then considers a range of examples taken from key therapeutic areas like haemophilia care and cancer service provision. The former is an important

example because of the volumes of relatively expensive replacement blood Factors needed by comparatively small numbers of patients to protect them against disabling and on occasions potentially fatal bleeds, and the fact that there are continuing opportunities to improve outcomes. Finally, a number of ways in which NHS medicines procurement practices – which are already amongst the most advanced in the world – might be further improved are discussed, and reform options considered.

The UK's future relationship with the EU is presently uncertain. The June 2016 referendum decision to leave the Union might eventually lead to questions about issues such the viability of University biomedical research in this country and the continuing capacity of the NHS to offer comprehensive taxation funded health care. But what is more certain at the moment is that the need to contain spending in order to withstand what could prove to be escalating pressures on NHS and wider public finances should as far as possible be met in ways that encourage innovation. Efforts to contain costs should be consistent with preserving the standing of countries like England and Scotland as good places in which to invest and go on improving medicinal and other products and services.

Two other introductory points deserve emphasis. The first relates to the fact that in all advanced economies public purchasing is accounting for a growing share of total economic activity. In Europe as a whole it now represents in the order of 16 per cent of the Union's GDP (European Commission, 2014), or about €2.3 trillion per annum¹. The equivalent figure for the UK is in excess of £230 billion – Cabinet Office, 2015. Expenditure at this scale has the potential, if not undertaken in an appropriately directed manner, to seriously distort future patterns of economic and social development.

Compared with the overall value of public procurement the total amount spent on medicines and associated items such as vaccines is modest, although still significant in absolute terms. EU wide it stands at about €200 billion annually, or around 1.5 per cent of the European Union GDP (OECD, 2015). The proportion of Britain's national income spent on NHS medicines and allied goods is approaching 1 per cent. Of the overall amount spent on pharmaceutical products in this country under a half involves purchasing via direct NHS tendering. This is because the great majority of community supplied medicines are bought by local pharmacies from national wholesalers, or on occasions directly from manufacturers or other intermediate sources.

The impacts of tendering for medicines used in centrally funded specialist care can be especially influential, in as much as the State (or its agent) is in effect acting as the sole purchaser of key treatments used within

its borders. In areas such as rare disease care robust working partnerships between medicine manufacturers and clinicians, supported by 'expert patients' and their representatives, can be particularly valuable².

As compared to high technology goods like, say, computers, jet engines and other complex engineering products, medicines are normally composed of just a few key substances and can from a technical standpoint be easy for expert manufacturers to copy, even though this is less true of some biologically based treatments than it is for those with small molecule 'active pharmaceutical ingredients' (APIs). Such observations underline the fact that a high proportion of the value of innovative medicines lies in the 'know-how' associated with their clinical development and optimal therapeutic use. It is also worth noting that the modern therapeutic armamentarium now involves many thousands of medicinal drugs and allied products. Those purchased in low volumes and low controlled prices are likely to be particularly difficult for commercial suppliers to provide on a sustainable basis without periods of unavailability.

The shift towards more personalised treatment

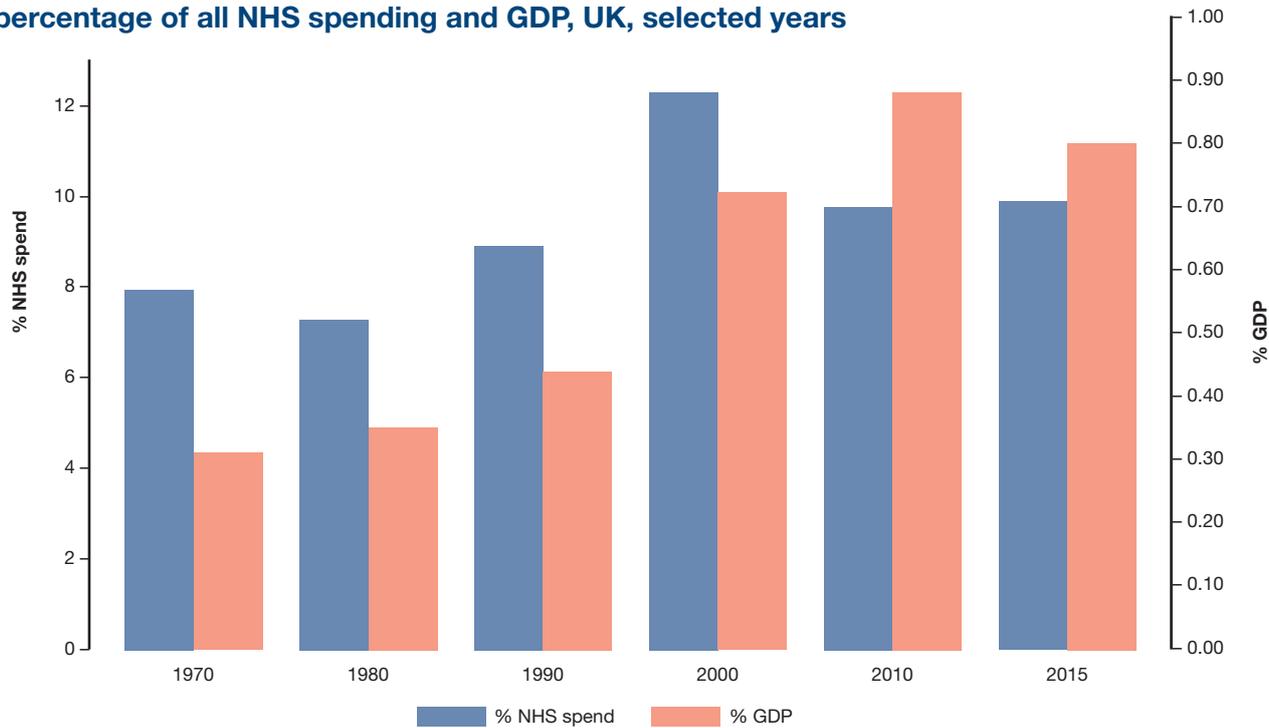
The second set of factors worth highlighting relates to the changing nature of the pharmaceutical market. As the focus of scientific innovation becomes more concentrated on developing targeted, often large biological molecule based, treatments for relatively small user groups, so the proportion of patients being cared for via hospital based or other specialist centres is tending to rise. With this shift from primary care it appears inevitable that over time there will be a corresponding increase in the proportion of NHS medicines procured via tendering as opposed to methods such as 'spot purchasing' by independent contractors.

People whose jobs centre on limiting costs and keeping within defined budgets must be highly sensitive to product prices and volume usages. Especially in periods of austerity, pharmaceutical spending is in political and public debate terms highly visible. Yet even today it accounts for little more than a tenth of overall health service costs in net terms. This proportion has remained (mainly because when their intellectual property rights expire the prices of medicines and allied goods normally fall towards commodity levels) at around this level for about half a century – see Figure 1.

¹ Based on the World Bank estimate that the EU's GDP stood at just over US \$ 16 trillion in 2015

² When only one branded medicine supplied by a single producer is available for treating a condition tendering based procurement – which demands competition – is not a viable option. In some circumstance NICE is *de facto* responsible for defining prices in England and Wales via the negotiation of Patient Access Schemes (PASs). In others NHS England may as the national service commissioner elect to specify the amount it is prepared to pay for the treatment of a given number of NHS patients.

Figure 1: Total NHS medicines spending at manufacturers' prices as a percentage of all NHS spending and GDP, UK, selected years



Source: OHE various years, 2015 estimated

Alongside the centrally led purchasing of treatments, enhanced drug targeting is also driving interest in the concept of 'personalised care'. This by definition requires clinical excellence in the shape of sensitivity to variations in individuals' treatment responses. Hence pharmaceutical procurement programmes fit for the 21st Century must constantly seek to balance affordability concerns and the financial advantages of 'one size fits all' treatment options with an awareness of the potential for optimised pharmaceutical care strategies that are tailored to meet each individual's needs in order to improve outcomes, and to maximise the welfare linked returns to health service investment.

Policy drivers and procurement systems

Well informed public procurement strategies help drive quality improvements and economic growth. Using the purchasing power of States for the public good – which includes encouraging fair competition, promoting innovation, protecting the environment and obtaining maximum direct benefit from taxation funded spending – was the fundamental aim of the European Public Procurement Directive. It was transposed into UK (English, Welsh and Northern Irish) law as the Public Contracts Regulation in February 2015. Additional Regulations on concession contracts and utilities were passed by the UK Parliament in March 2016. Further aspects of the Procurement Directive's goals are considered in Box 1.

Despite the possible long term consequences of the recent 'Brexit' referendum result, in the next few years no significant changes in procurement policies and practices are likely to result from it. Although international companies and other investors may no longer see London – or England more broadly – as a valued gateway to the EU market, it will remain vital for Britain to continue to offer a desirable setting for research and the introduction of new products and services.

If the UK exits the single market one result will almost certainly be an end to the promotion of and access to British public contracts for companies resident in EU countries, and vice-versa. Yet even in this case it is possible that mechanisms to allow the continuation of trading activities could be instituted via a future 'deal' covering both goods and services provision. Developments along these lines have been discussed in the Transatlantic Trade and Investment Partnership (TTIP) negotiations between the US and the EU, albeit progress in this context has been slow and may be at some point be halted altogether.

Some observers are predicting that the British economy will slow, or might even enter a recession, in 2017. If this proves to be the case procurement strategies could gain increased attention for two main reasons. Firstly, a drop in tax receipts would in time be likely to herald further fiscal belt-tightening and public spending curbs, leading to the possible use of public procurement interventions to drive down costs. However, the consequential impact of this on competition, choice and added-

Box 1. The 2014 EU Procurement Directive – supporting economic success by ‘buying innovative’

In 2005 European Heads of State met in the UK at what came to be known as the ‘Hampton Court Summit’. They decided that more attention should be paid to the challenges of globalisation, one of which links to supporting research and industrial innovation. This subsequently led the European Commission to ask a group chaired by the former Prime Minister of Finland, Esko Aho, to assess the situation and suggest ways of boosting Europe’s performance. The resultant Aho Report (European Communities, 2006) identified an urgent need to ‘act before it is too late’. Its proposals involved ‘the creation of innovation friendly markets’ as well as increasing R&D spending and fostering ‘a culture which celebrates innovation’.

It was this initiative which in large part prompted the development of the legislative package on public purchasing contained in the revised 2014 Procurement Directive. The fundamental aim of the latter is to help ensure sustainable economic growth. Even if the UK is to eventually leave the single market this objective will remain at the centre of the national policy agenda.

As discussed in the main text, an important element of the strategy adopted was its encouragement of the ‘Most Economically Advantageous Tender’ (MEAT) approach. Through this public authorities ought to be able to place an increased emphasis on product quality and entire life-cycle cost optimisation, as against price minimisation focused purchasing. The future challenge facing organisations like the NHS relates to putting this good intention into practice in ways that are consistent

with sometimes conflicting public interests in immediate cost saving (which often urgent end can overwhelm other objectives) as opposed to seeking long term welfare and economic development. The Directive’s other important goals included:

- **simplifying rules and procedures in order save not only money but also time.** For example, in areas where competition is difficult to achieve it introduced ‘light touch’ flexibilities which allow purchasers to enter into dialogue with potential suppliers without going through a full procurement process involving what is known as ‘prior publication’;
- **encouraging the formation of Innovation Partnerships between public and private organisations in contexts where there is a recognised need for new and more effective products.** Looking forwards, one opportunity for the NHS could be (in order to strengthen the implementation of MEAT based purchasing) to accept that innovation in health care also depends on improved practices, and to recognise the roles that private sector partners play in supporting care quality improvement; and
- **extending opportunities for small and medium size enterprises (SMEs) to win income from large public tenders.** This can be achieved through, for instance, dividing contracts into lots and monitoring performance in this and other fields.

value generation might in such circumstances prove regressive. A second, more positive, possibility could therefore involve the use of public procurement policies in various sectors as strategic tools for encouraging innovation and investment in Britain.

Regardless of the impacts of the 2016 referendum decision, both the UK and the European Union still face significant challenges in overcoming the aftermath of the 2008 financial crisis and responding effectively to fast changing world conditions. It is probable, for example, that 21st century ‘mega-trends’ such as the growing ‘electronic connectedness’ between people and increasingly rapid flows of capital and information across national and regional borders will facilitate shifts in the global economic centre of gravity towards the emergent economies of Asia and elsewhere. At the same time population ageing brought about by low birth rates and coupled with extended life expectancy will also create new needs and opportunities in every part of the world. These will change health care requirements and the provisions made to meet them, and further increase the importance of improving productivity in all sectors of the ‘mature’ economies.

Such observations link back to the role of procurement policies in supporting innovation as well as in curbing costs. In seeking to respond to macro-level challenges the European Commission published the EU 2020 Growth Strategy in 2010. It confirmed the policy direction identified in the 2006 ‘Aho Report’ and the advantages of developing a ‘smart growth’ economy based on knowledge building and innovation as one of three key objectives.³ Targets relating to achieving this include investing 3 per cent of the EU’s GDP in R&D by 2020 – the 2014 average was 2 per cent.

The UK is presently committed to delivering this strategy, though Britain lags behind other large economies with respect to investment in R&D. The latter currently stands at 1.7 per cent of GDP for the nation as a whole (ONS, 2016). This compares to 4.1 per cent in South Korea, 3.5 per cent in Japan, 2.9 per cent in Germany, 2.8 per cent in the US and 2.3 per cent in France (Eurostat, 2016). Such data highlight the fact that despite initiatives like, for

³ The other two being ‘sustainable growth: promoting a more resource efficient, greener and more competitive economy’; and ‘inclusive growth: fostering a high-employment economy delivering social and territorial cohesion.’

Box 2 The Pharmaceutical Industry as a UK National Asset

Spending on medicines and allied products by the NHS is sometimes presented as being only a cost to taxpayers. However, apart from the health gains their products generate, recent data show that British and other pharmaceutical companies deliver what economist term a gross value of around £8 billion to the UK, along with a £3 billion positive contribution to the balance of trade.

The research based pharmaceutical industry accounts for about 25 per cent of all UK private sector R&D spending (pharmaceutical companies currently spend some £4 billion a year on British based projects) and employs over 70,000 people. Although this is a relatively small workforce number compared with areas such as high street retail, it means that in per capita terms pharmaceutical company employees contribute more to the UK economy than those working in any other major sector. Industry returns also contribute to pension funds and the work undertaken by Universities and voluntary sector organisations.

instance, Innovate UK and the creation of 11 so-called ‘catapult centres’ intended to support rapid progress in key research areas, Britain has even within the EU lacked a world-class record in overall research funding.

Outside biomedicine linked areas this country's record in translating fundamental research into the supply of commercially successful ‘high technology’ goods is also patchy. The UK trade balance with the rest of the world with regard to the latter is negative. Pharmaceuticals can be regarded as an exception to this generally disappointing picture (Box 2). But for the purposes of this analysis it can be argued that unless communities are prepared to spend adequately on not only publicly and charitably funded basic research but also on science based products offered on their domestic markets they may in time lose out to more favourable environments.

Medicines Purchasing in the English NHS

Policy makers have become increasingly aware of the leverage public spending can have in changing business practices. Over and above the benefits already referred to, high quality procurement strategies can serve as tools to promote transparency and discourage corruption, and improve business to business transaction standards in fields such as late payment avoidance and taxation related fraud reduction. In *Managing Public Money* (July 2013, revised August 2015) HM Treasury (2015) set out principles for good procurement across Government in ways consistent with national and EU Law and World Trade Organisation (WTO) agreements. It reiterates the view that obtaining value for money ‘*means securing the best mix of quality and effectiveness for the least outlay over the period of use of the goods or services bought. It is not about minimising up front prices.*’

Domestically, the UK is already a relatively low spender on pharmaceuticals. It is possible that the NHS will in future identify new ways of spending less on products such as branded medicines. This could generate not only health sector savings but also some costs for the wider UK economy.

Were the contributions of assets like the UK based pharmaceutical industry to decline in the post Brexit era the overall NHS budget might also have to fall, leading to more pressures on care standards and costs. Such observations underline the importance of ensuring that in all areas of medicines procurement and supply strategy appropriate mechanisms are in place to prevent the misuse of single-purchaser powers in ways that undermine public interests in ensuring that short term health service cost savings are not pursued at an undue price for the community as a whole.

This document then goes on to say that ‘*whole life cost*’ rather than lowest purchase price is a key factor in determining value. For example, if one product is significantly more durable than another or if in the health arena a ‘*product plus service*’ offer is cost effectively associated with superior long term outcomes this should guide buying decisions, even if immediate costs are raised.

In May 2012 the Department of Health published *NHS Procurement: Raising our Game (RoG)*. This provided the NHS with guidance on steps to be taken to improve procurement in the NHS. It aimed to ‘*modernise procurement in the NHS, take advantage of its enormous buying power, ensure value for money for taxpayers, develop more productive relationships with industry, and provide patients with better access to the very best services, technologies and medicines.*’ More recently Lord Carter of Coles (Department of Health, 2016) emphasised the scale of the savings that enhanced procurement practices can generate in the hospital sector, which utilises two thirds of all NHS resources. He highlighted the significance of pharmacy in not only assuring NHS medicines supply but also optimising their clinical application. From an economic perspective the gains achievable from better drug usage often outweigh savings to be achieved via means like price cuts.

Pharmacy opportunities

Historically, pharmacists were central to making medicines until the period between the First and Second World Wars. Subsequently, as the twentieth century continued to unfold, they took on the role of purchasing finished pharmaceutical products from manufacturers and distributing them to the public via community and individual hospital pharmacies. But in the modern

context clinical pharmacy is becoming more important. The expertise of pharmacists in knowing what medicines to buy from which sources still has value. Yet a range of additional institutional mechanisms and practitioner skills are now involved in controlling the prices paid for pharmaceuticals and the volumes purchased, as well as regulating their quality and overall cost to the health service and the tax payer.

Notwithstanding discounts, public spending on NHS medicines currently stands at around £16 billion, or some 13 per cent of total health service costs in England (2016 gross figures). Some 75 per cent of this sum is spent on branded medicines, with the remainder meeting the cost of generics and so-called 'specials' (ABPI, 2016). Of the total quantum of medicines dispensed every year a little over half by value are now prescribed and supplied through primary care. The remainder are hospital pharmacy provided. This last proportion has been gradually increasing since the start of the 1990s, when it was only a little over 20 per cent.

The available evidence indicates that the UK is in overall terms one of the lower priced markets for medicines in Western Europe. Its total spending on pharmaceuticals expressed as a percentage of national wealth has been relatively well controlled, albeit that as the costs of primary care medicines have declined hospital drug budgets have been placed under new stresses via a combination of spending restraints and the advent of new opportunities for treating seriously ill people.

Ever since the creation of the NHS there has been national level recognition of the value of pharmaceuticals to both public health and the economy as a whole. This is not least because of their export potential. Balancing the need for health care affordability and industrial and commercial success has been central to the UK Pharmaceutical Price Regulation Scheme (PPRS) since its inception in the 1960s⁴. Despite criticisms made by bodies such as the Office of Fair Trading (OFT, 2007) at a time when there was political pressure for the institution of a more 'product by product' focused approach to determining pharmaceutical pricing and costs, it can be argued that the PPRS approach has had a number of unique strengths. They exist in relation to limiting the total amount of money spent by the NHS on medicines and allied products and rewarding innovation without imposing needless costs or damaging the pharmaceutical industry in this country or more widely (Taylor and Maynard, 1990).

4 The origins of modern PPRS can be dated back to 1957, when what was at first called the Voluntary Price Regulation Scheme (VPRS) was established. It initially linked domestic and export prices, on the assumption that 'non-market' NHS willingness to pay should be guided by world free market standards. However, since the formation of the PPRS in the 1960s it evolved as a relatively tightly managed system for controlling corporate profitability and industrial activity costs.

Capping total outlays

The PPRS is a non-contractual agreement negotiated by the Association of British Pharmaceutical Industry (ABPI) on behalf of its participating members with the Department of Health, acting with a UK wide brief. Today, it is the primary tool for managing branded medicines costs in the UK. It is normally re-negotiated every five years and the 2014 version will terminate at the end of 2018.

The PPRS regulates the income that companies can achieve on sales to the NHS, rather than controlling individual products' launch prices directly. Yet it does not guarantee any given amount of return. The calculation of permissible company earnings involves setting a range of allowances covering R&D, manufacturing costs, information, sales and marketing, and general administrative costs. Unless exemptions have been agreed because separate supply contracts have been signed the PPRS applies to all branded pharmaceutical products sold to the NHS, with or without patent protection. It covers vaccines, blood products and biotechnology products including biosimilars, as well as more conventional medicines. By contrast, non-branded generic medicines are not covered by the PPRS, in large part because it has been (in rare instances questionably) assumed that competitive forces will keep their prices within appropriate boundaries.

The 2014 PPRS reaffirmed both the Department of Health's and the ABPI's support for the approach described in *'Innovation, Health & Wealth'* (IHW), the DH's 2011 strategy for developing an "NHS defined by its commitment to innovation, demonstrated both in its support for research and its success in the rapid adoption and diffusion of the best, transformative, most innovative ideas, products, services and clinical practice." Amongst other innovations the 2014 agreement established UK PharmaScan as a NICE hosted data base. It helps both NHS organisations and registered companies understand the likely financial and health impacts of new products before they reach the market. However, the most important facet of the current PPRS is arguably that, over and above profit and cost limits, it limits the total amount of money that pharmaceutical products covered by it cost the NHS. 'Overspends' are returned to the DH (Box 3).

NICE's role

Over and above the PPRS, the National Institute for Health and Care Excellence has since 1999 played an important role in limiting medicine prices low through, amongst other functions such as the production of evidence based treatment guidelines appraising the cost effectiveness of selected innovations. On the basis of such calculations NICE may or may not recommend their

Box 3. The Pharmaceutical Price Regulation Scheme

From its original establishment as the Voluntary Price Regulation Scheme (VPRS) in the late 1950s through to its current format, the UK PPRS has evolved to embody a progressively more sophisticated set of mechanisms for moderating total NHS spending on branded medicines. Some critics argue that it is no longer needed, in part because the costs of medicines purchased via tendered contracts are not normally included in the PPRS returns made to the Department of Health. But its proponents believe that it helps to deliver cost restraint without counter-productively damaging public and private interests in pharmaceutical innovation.

The PPRS links the research, manufacturing, marketing and management costs incurred by companies supplying pharmaceuticals to the NHS to the returns on the capital that they employ. It places ceilings on both profits and their outlays in areas such as promotion, while allowing companies the power to set the prices of innovations. The current version of the Scheme also controls the overall amount of money PPRS companies can earn on sales to the health service, with 'over-spends' being returned to the Department of Health.

The arrangements governing these re-payments have been controversial in England because the funds involved have not been visibly returned to the hospitals or commissioners responsible for making the original payments. This may be seen as creating perverse incentives for care providers not to invest in innovative treatments, even when the net cost to the health service of using better therapies is negligible.

The situation has also since 2000 been complicated by the existence of NICE, and its indirect role in fostering a form of value based pricing for selected products. However, the most important point to stress is that the PPRS explicitly acknowledges that it is not concerned with price minimisation but rather seeking to achieve a robust balance between cost control and investment in innovation. Whatever the future of the Scheme itself, the preservation of this principle in all aspects of NHS pharmaceutical purchasing should arguably be seen as a desirable goal.

use in the NHS. NICE is not directly involved in setting prices, and nor does it seek to determine whether or not the NHS can afford to implement its recommendations.

There is some controversy regarding the extent to which NICE's interventions have been cost saving for the NHS as a whole. However, the organisation does play a clear role in limiting the amounts spent on some individual products via its influence on the terms of Patient Access Schemes (PASs). These can foster better care but in large part serve as mechanisms for companies to discount the *de facto* prices paid by the NHS for the use of innovative treatments without cutting their list prices.

Promoting timely access to better treatments

The work of the Accelerated Access Review of Innovative Medicines and Medical Technologies (AAR) is potentially important in this last context. Initially launched in November 2014 and chaired by Sir Hugh Taylor, the aim of the AAR is to "...*make recommendations to government on reforms to accelerate access for NHS patients to innovative medicines and medical technologies (including devices and diagnostics), making our country the best place in the world to design, develop and deploy these products*" (AAR, 2014). The review has looked at, firstly, how regulation can be adapted to speed up the assessment of new medicines and devices; secondly, how reimbursement can evolve to aid innovation and how health economic

evaluation should consider new advances in genomics and informatics; and, finally, how the NHS can support medical innovation through mechanisms like specialist commissioning.

This initiative raises a number of important questions in areas like how best patients and service users can and should be involved in the processes of therapeutic innovation. But from a medicines and allied product procurement perspective its most important implications are linked to the need to weigh the benefits of price minimisation against a full awareness of the value of continuing to provide incentives for investing in biomedical innovation, and for forming partnerships aimed at optimising the outcomes derived from both new and established forms of treatment. In what may become an increasingly testing fiscal and public spending environment the importance of achieving a robust balance between affordability and research and development investment will probably grow.

It would be understandable if in the next five to ten years NHS budget holders with procurement responsibilities were to become increasingly focused on reducing costs, regardless of other concerns. Yet from a high level policy perspective this could risk exacerbating rather than relieving the nation's long term economic challenges.

Purchasing for improved outcomes – the MEAT challenge

The NHS in England currently costs in the order of £120 billion annually. Some two thirds of this spending total takes the form of professional and other staff salaries and associated outlays. Yet most of the remainder involves the procurement of externally produced goods and services from many thousands of different suppliers⁵. Although when all discounting is allowed for drugs and related items account for little more than a tenth of overall health care costs, pharmaceuticals represent the second largest discrete NHS expenditure category after labour payments.

In the community setting medicines and allied products are supplied via local pharmacies. As already described, they purchase most of the pharmaceuticals they dispense via national level wholesalers within the price limits set by the 'Drug Tariff' in the case of generic medicines and the PPRS in the case of most branded products. However, supplies are also obtained from other sources. Community pharmacists are encouraged to pursue discounts on the medicines they obtain for NHS supply, albeit there is a 'clawback' system in place which seeks to ensure that the taxpayer enjoys a reasonable share of such savings/earnings.

In the hospital sector expertise in tender-based medicines purchasing has accumulated since the 1950s, initially in individual hospital settings and subsequently at the regional and national levels. Pharmacists and their local procurement team colleagues have also been central to this aspect of medicines buying, although recent changes in the commissioning and working of the NHS Specialist Pharmacy Service (NHS England, 2014) may well lead to further adaptations. The past involvement of local hospital pharmacists and other staff may on occasions have helped to facilitate clinician 'buy-in' to cost saving procurement decisions. Large scale, more impersonal, systems may save additional money, and strengthen the overall NHS's bargaining position relative to drug suppliers.

Tendering processes

Tendering for generic drug supplies has taken place in the NHS for over 30 years, and is also well established in many areas of branded medicines purchasing. It is of particular value in contexts when competition between like or substitutable items is not generating desirable

economies. Tendering proposals should have a clear scope, and be robustly linked to the budgets available. Supply durations should be well-defined, as should specifications for the goods and services that successful providers will be expected to deliver. Problems associated with tendering and allied activities can include:

- purchasers and/or policy makers having inadequate knowledge of the products or services to be procured, particularly in 'real world' contexts and that of end-point users' highest priorities;
- purchasers lacking the professional skills required to secure best-value;
- lack of transparency on the part of suppliers and difficulties linked to inadequate awareness of tender calls, resulting in failures to ensure adequate competition; and
- failures to employ procedures best suited to obtaining optimal outcomes.

The awarding of contracts based on price is normally approached by either comparing the initial capital costs of accepting alternative bids, or through evaluations of rival products' and services' whole life projected costs. As has already been discussed, the problem with the former approach is that immediate price advantages alone do not guarantee best value. 'Whole life' analyses allow more consideration of the total costs of choosing one product or service over another, but even these can miss important aspects of value.

Because of growing awareness of the downsides of simplistic 'lowest price' purchasing strategies there has in recent years been a move towards adopting more sophisticated approaches, as reflected in the requirements of the 2014 Procurement Directive. Most Economically Advantageous Tender (MEAT) oriented strategies seek to take into consideration multiple criteria based on the qualities of the products or services available. These may include:

- price or cost, using cost-effectiveness based approaches;
- technical merits, such as storage properties and functional properties;
- safety related variables;
- aesthetic characteristics;
- accessibility;
- social and environmental characteristics;
- innovative characteristics;
- after-sales service and technical assistance availability; and
- delivery conditions, such as supply dates and processes. (See, for example, Association of Colleges, 2016).

⁵ The Carter Review of Operational Productivity and Performance in English NHS Acute Hospitals sampled the procurement activities of 22 Trusts. They found they used 30,000 suppliers, 20,000 different product brands, 400,000 manufacturer product codes and more than 7,000 people able to place an order.

Weightings can be applied to each of the criteria used and an overall score on the suitability of the supplier and the products or services being purchased then calculated. However, this can in practice be difficult to achieve in a manner acceptable to all the stakeholders involved in procurement processes. Legal restraints and related fears can also inhibit behaviours. Partly because of this the forces favouring 'lowest price at any cost' purchasing as opposed to value-based procurement can be hard to overcome.

This might, for example, have on occasions proven to be the case in respect to providing social care for elderly and other vulnerable individuals. Achieving due sensitivity to both personal needs and wider community interests may be even more difficult in fields like medicines supply, unless an appropriate balance between serving patient and public welfare focused professional interests on the one hand and the pursuit of cost reduction targets on the other can be maintained.

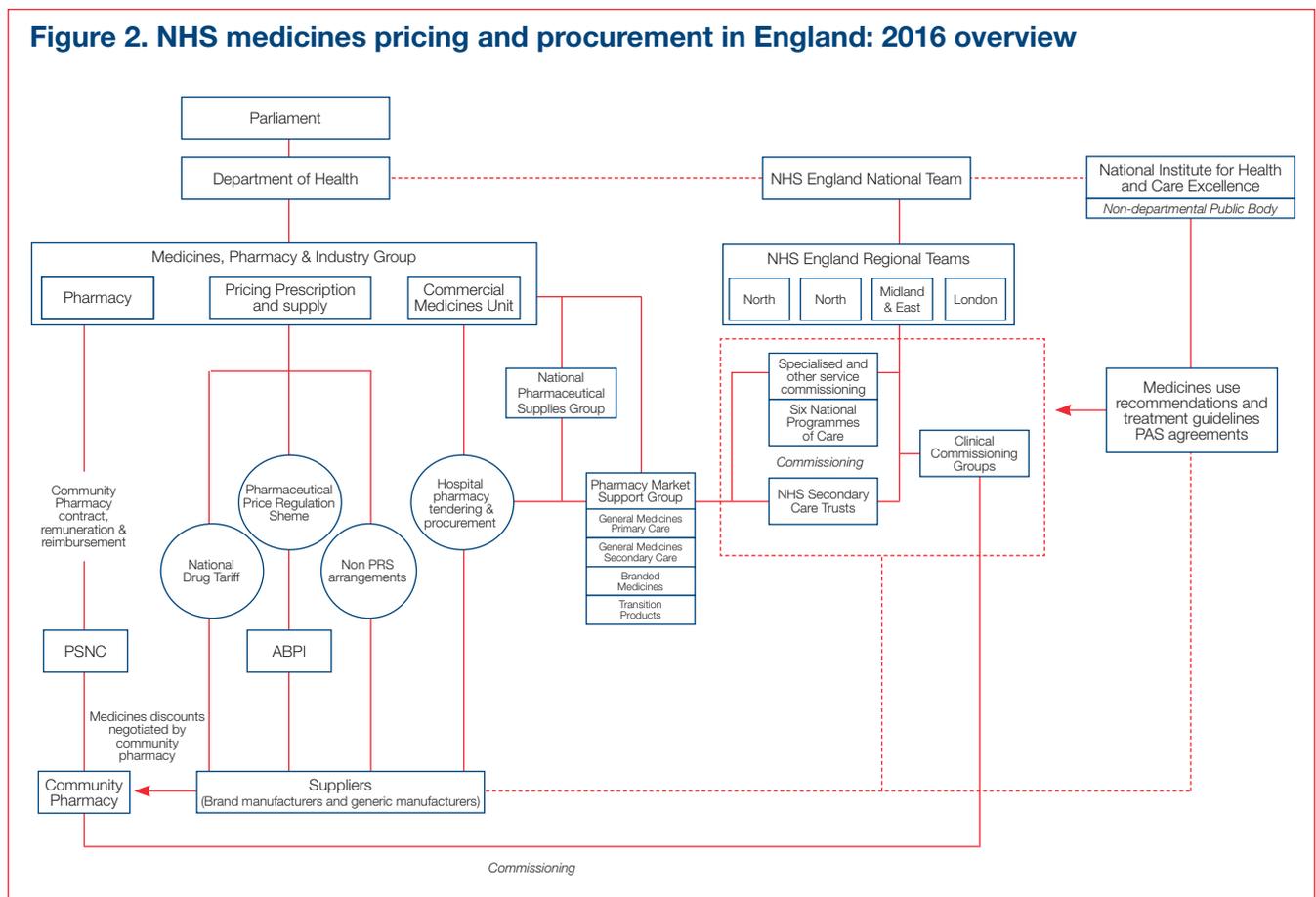
Centralised direction

Tendering has had a significant impact on medicine prices in secondary care, not least in fields where previously they varied widely between localities because of factors such as differing demand volumes and purchasing expertise levels. As already described it can be undertaken locally and regionally, but is increasingly being organised nationally with (in England) the support of a central DH

procurement team called the Commercial Medicines Unit (CMU). Centralised purchasing has arguably been most productively employed in areas such as HIV and haemophilia treatment, where relatively low volumes of high unit cost medicines are supplied to patients via limited numbers of specialist centres.

The CMU was originally part of the NHS Supply Agency and subsequently the Purchasing and Supplies Agency (PASA). It has since then been taken forward as a part of the Department of Health's Procurement Investment and Commercial Division, although recently there have been suggestions that it should be hosted by NHS England. In addition to facilitating the acquisition of both branded and generic medicines for hospital use, the CMU supports the procurement of homecare – where there have reportedly been some recent concerns about the withdrawal of a major provider – and also vaccines⁶. Other bodies that play important roles in NHS medicines purchasing include the National Pharmaceutical Supplies Group (NPSG), which is made up of secondary care chief pharmacists together with a range of other senior colleagues, and the Pharmacy Market Support Group (PMSG – see Figure 2).

⁶ Vaccines are purchased centrally in bulk by the Department of Health, as are products to be stockpiled for emergency use and supplies of Intravenous Immunoglobulin (IVIG). This last is a blood product. From a procurement perspective the special status of IVIG can be linked to historic concerns about supply continuity and the impacts of the introduction of bioengineered blood factors on the economics of its production.



The English medicines procurement structure can be expected to evolve alongside that of the NHS Specialist Pharmacy Service. The PMSG's role has been described as being centrally concerned with implementing the strategic plans agreed by the NPSG and to monitor locality level performance and compliance. PMSG subgroups have been responsible for differing segments of the medicines market, including generic products, biosimilars, pharmacy business technology and branded medicines. It is of note regarding the latter that branded medicines subject to central tendering are normally removed from the scope of PPRS returns in order to avoid manufacturers facing a double burden of price reductions and profit limitations.

It would be outside the scope of this report to offer a detailed analysis of how tendering processes must be conducted in order to comply with EU and UK public procurement laws. But in outline the present situation is that they should initially be advertised in order to communicate the identity of the procuring authority and describe the type of good/services being sought, the duration of the contracts to be offered, how awards will adjudicated and any specific conditions with which a successful supplier must comply. Above a certain value threshold tenders have to be openly advertised through the OJEU system, although this will probably change if Britain leaves the European single market.

Box 4. The Value of Multiple-supplier Framework Agreements

Multiple-supplier Framework Agreements embody all the terms and conditions for purchases agreed between a contracting authority and its suppliers without necessarily placing an obligation on the purchaser to buy any given overall volume of goods or services. According to one leading law firm 'a *Multi-supplier Framework allows a contracting authority to select from a number of suppliers for its requirements, helping to ensure that each purchase represents best value.*'

Contracts are formed and are subject to procurement regulations once relevant products or services have been purchased (that is, once 'call-offs' are made). According to the now dissolved Office of Government Commerce '*the benefit is that, because authorities are not tied to the Agreements, they are free to use the Frameworks when they provide value for money, but to go elsewhere if they do not.*' In the NHS context MsFAs also help to preserve clinical and patient choice within a structured price and cost environment. If the process involved allows branded medicine suppliers to charge at different levels depending on the amount of goods purchased from them in any given period they too enjoy an element of enhanced security. Their unit returns will tend to be inversely related to the total volume supplied.

Following this, a pre-qualification phase allows potential suppliers to register their interest and demonstrate eligibility for participation. Companies meeting the relevant criteria receive an Invitation to Tender (ITT), accompanied by further information. The final stages of the procurement process consist of reviewing and assessing the tender offers against the stated criteria and notifying the successful and unsuccessful suppliers. A mandatory standstill period of 10 days allows any supplier that feels it has been unfairly treated to challenge the decisions made.

As is explored further below, different tendering process designs exist. Selecting the most appropriate methodology enhances the bargaining power of procurers. In addition, Multi-supplier Framework Agreements (see Box 4) can ensure flexibility for purchasers operating in complex settings like the NHS, where each individual body offering a given service may need varying amounts of alternative products.

Recent developments in procurement techniques, in part made possible by modern information and communications technology, have strengthened the positions of drug and allied product buyers as against their suppliers. Yet there is evidence from other sectors that in some circumstances the use of 'reverse auction'⁷ and other advanced tendering processes can damage useful aspects of buyer-supplier relationships and so perhaps threaten supply continuity or aspects of service quality. The next section of this report highlights some of the challenges to be overcome in relation to a selection of 'real world' examples drawn from the experience of the NHS in England.

Providing Specialised Treatment for Children and Adults

Specialised care is an umbrella term which refers to services provided in a limited number of hospital and allied centres, typically for patients with relatively rare conditions requiring high cost interventions. Those in need of such medical and related health professional support include many of the most vulnerable children and adults in the country. They are living with conditions ranging from, for example, renal failure and forms of incontinence requiring corrective surgery through to diseases such as childhood cancers, cystic fibrosis and early-life mental health problems, as well as life threatening blood disorders and infections like HIV and Hepatitis C. A proportion of the people with these

⁷ Reverse auctions involve iterative processes in which rival providers of goods and services make bids relating to the amount they are willing to accept for given volumes of substitutable product, at the end of which the lowest cost provider wins either the entire contract or the largest share of the supply contract on offer.

last diseases need treatment for them because until a decade or so ago they received from the NHS products for haemophilia and linked conditions that contained live viral contaminants.

Specialised services currently cost NHS England approaching £16 billion a year. This total (around 15 per cent of which is being spent on high cost medicines and associated products) is comparable to the health service's gross spending on pharmaceuticals of all types. The English NHS reforms that came into effect in 2013 imposed some re-organisational costs and had disruptive impacts in various areas, including the commissioning of specialised services (National Audit Office, 2016). This created considerable concerns about financial control. Public attention was particularly directed to the cost of the Cancer Drugs Fund (CDF), albeit it accounted for no more than 3 per cent of NHS England's specialised commissioning outlays in 2015. Emergency measures to stem over-spends may in some instances have adversely influenced the quality of care available to NHS users.

However, fit-for-purpose specialist care commissioning arrangements are now emerging. Six National Programmes of Care (NPOCs) are in place, each of which is led by a Board charged with coordinating and prioritising the activities undertaken within their respective fields. Each NPOC is associated with a number – typically around 10 – of Clinical Reference Groups (CRGs) that enable clinicians to advise on how services should be provided in their areas of expertise and can support the functioning of Framework Agreements. The six National Programmes cover:

- internal medicine, including specialist circulatory disease care;
- cancer;
- mental health;
- trauma;
- women and children, which includes a range of congenital disorders; and
- blood and infections.

Purchasing blood factor products for people living with haemophilia

Haemophilia is located in the last of these groups. It is in fact a small set of related inherited disorders. In the nineteenth and early twentieth centuries haemophilia received more attention than might have been expected for a rare condition because of the relative ease with which bleeding events can be diagnosed and the dramatic impacts it had on several of the Royal families of Europe, most notably that of the last Romanoff Tsar.

Haemophilias are genetic disorders which impair normal clotting, and so to differing degrees render affected individuals subject to damaging, sometimes fatal or permanently disabling, episodes of bleeding. For instance, inadequately treated individuals may suffer joint destruction which is not amenable to surgical correction. The more common forms are sex linked because they involve mutations in genes on the X chromosome, of which men only have one copy. They are only very rarely diagnosed in women, who need to have both their gene copies (alleles) affected before experiencing symptomatic illness. Females much more often act as carriers, passing the disease on to one in every two of their male children.

The most common form is Haemophilia A. It affects about 5,000 individuals in the UK and can be treated by giving subjects replacement blood Factor VIII. This can be either extracted from donated blood or produced artificially via recombinant technologies. The same applies in the case of Haemophilia B, which is rarer – there are about 1,000 cases in this country – and is caused by Factor IX deficiency⁸.

Typically, people who have one per cent or less of the blood Factor level typically present in healthy individuals are classified as having severe haemophilia, although in some cases patients have abnormally formed blood Factors rather than low levels. Those with 1-5 per cent of the reference level are likely to be diagnosed as having moderate disease, albeit some independent authorities argue that the 'severe' threshold would be better set at 3 per cent or less of the expected factor level (Kenny, 2016). Men and on rare occasions women who have between 5-40 per cent of the normal Factor level are normally classified as living with mild disease.

Up until the start of the 1960s boys born with severe haemophilia were unlikely to live far into their teens – the median age of death was about 10 years. But from about that time onwards blood Factor concentrates derived from donated supplies (including commercially sourced blood from the US) became available. Average life expectancy for people with severe haemophilia quickly rose to over 50 years. However, from the 1980s onwards increasing numbers of patients in the UK and other developed countries contracted HIV and/or other iatrogenically transmitted (that is, treatment caused) infections, including various forms of hepatitis.

Despite the health hazards known to be associated with conventionally sourced biological products the NHS was, in part because of cost concerns, relatively slow to adopt the use of recombinant Factor VIII and IX products. These

⁸ Haemophilia C is due to a mutation that is not located on the X chromosome, and hence is found equally in males and females. It involves reduced levels of factor XI, and is like a number of other genetic disorders unusually common in Jewish people with East European backgrounds who in certain phases of history – like many Royals – traditionally lived with an unusually restricted choice of reproductive partners. It is likely that Queen Victoria was born with a spontaneous mutation that gave rise to Haemophilia B in some of her male descendants.

Box 5. Purchasing Blood Products in Eire

The Irish Haemophilia Society was founded in 1968 by doctors and people living with haemophilia, together with their families and friends. They wanted to improve the quality of services available. The Society was initially influential in the establishment of specialist centres for supplying the blood Factor replacement treatments then becoming available in volume, and from the early 1980s in defending the interests of individuals who became infected with HIV as a result of using contaminated biological products.

In 2003 the Irish government, with support from and the continuing involvement of the Society, established a Haemophilia Product Selection & Monitoring Advisory Board (HPSMAB) to advise and make recommendations on the selection of products for the treatment of haemophilia, von Willebrand's disease (which is caused by an abnormal Gene on chromosome 12 that affects platelet functioning – it is the most common form of hereditary blood-clotting disorder) and related conditions. In these contexts it conducts National Procurement Tender processes.

To this end the Irish HPSMAB has produced, for instance, a pioneering score sheet to facilitate the purchasing of Factor VIII products for people living with Haemophilia A. This has been recognised as a robust example of how the MEAT criteria can in practice be implemented by purchasers. It details the weights to be given in areas such as safety, technical efficacy, other quality variables, supply security and both clinical and consumer preferences on top of the price element. The latter only accounts for a quarter of the total number of points that may be awarded.

This example can be seen as an encouraging illustration of what can be achieved in serving even a relatively small national population. Its achievement is in large part attributable to the committed efforts of the Irish Haemophilia Society, although it should also be seen in the context of Eire's relatively strong and highly valued pharmaceutical manufacturing sector.

molecules, synthesised by bioengineered bacteria, first entered the US and EU pharmaceutical markets in the early 1990s. However, by the turn of the current century there was growing UK patient and professional awareness of the safety advantages of recombinant treatments. From 2005 onwards a new tendering approach was taken in order to support the procurement of such medicines for all in need of them in an affordable manner. It sought to ensure nationwide access to good quality supplies at a cost acceptable to the NHS.

The details of the procurement strategy adopted in three phases in the period 2004 and 2014 between have been described by Hay (2013). Developed with the close involvement of doctors working in specialised Haemophilia Centres across the country and supported by the Department of Health's Commercial Medicines Unit, this utilised a 'reverse e-auction' methodology. This incremental process required rival manufacturers to, over a period of time, bid down against each other for differently sized portions of the NHS requirement for recombinant Factor VIII and IX products. At the end of this process the lowest price supplier meeting the specified quality criteria was awarded the largest volume contract, with higher priced suppliers being awarded lower sales volumes.

This initiative (along with other tendering based procurement approaches pioneered in Ireland and elsewhere – see Box 5) is widely regarded as having been a success, although reverse e-auction tendering is not now widely used as compared to the alternative of asking would-be suppliers to submit single 'sealed-envelope' bids indicating the volume-specific prices

at which they are able to offer their products. A multi-provider Framework Agreement was subsequently established, via which individual Centres in England and the other UK nations were made (and remain) free to buy from nationally approved suppliers those haemophilia treatments their medical staff and their patients believe to be most appropriate for meeting their personal needs.

The benefits of centralised procurement should include reduced administrative outlays coupled with enhanced purchasing power. In the case of haemophilia care it may be estimated that annual savings of around a third have been secured on an original sales value of approximately £150 million, without sacrificing clinical autonomy or patient centred care principles in a manner unacceptable to the health professionals and NHS users involved. At the same time companies supplying Haemophilia Centres have a degree of security relating to the sales they will achieve during each contractual period, and the overall cost to the NHS is kept within a defined envelope.

The purchasing of blood Factor concentrates in the UK can therefore be taken to offer a positive example on which to build for the future. But a number of cautions should be noted. They include:

- *Haemophilia services are in some respects atypical*

Historically, blood products like biologically sourced Factor concentrates were not normally purchased via pharmacies, but directly by haematology departments or non-pharmacist purchasers working on behalf of haematologists. Now they are manufactured by companies using advanced bio-engineering techniques they may arguably be regarded as being more like

'normal pharmaceuticals', and so more within the realm of pharmacy. Even so, specialist haematologists can still be regarded as having a unique expertise in relation to such products. This atypical background, coupled with the need to address the special support needs of individuals and families living with haemophilia and the unique network of dedicated Centres that has been set up to help meet them, may mean that the high level of informed engagement shown by members of the UK Haemophilia Centre Doctors Organisation in the procurement process evolution outlined here could prove difficult to replicate in many other areas.

- *Treatment and purchasing approaches must adapt as new therapeutic technologies and strategies demonstrate an enhanced outcome potential*

For example, the use of blood Factor replacements with extended half-lives may open the way to a new balance between supplying long-term prophylactic interventions on a regular basis (needed in more severe cases, and which might benefit an increased number of individuals as and when their personal pharmacokinetic and treatment response profiles are better understood) and 'coagulation on demand' care when individuals are suffering identified bleeds. Intermittent Factor replacement treatment is normally the optimal choice for individuals with moderate to mild disease. To the extent that this is the case future, potentially more centrally controlled, prescribing and linked procurement strategies will when appropriate need to be flexible enough to accept higher unit cost product usage in order to generate better outcomes and release medium to long term financial savings along with increased patient wellbeing.

Ultimately, industrial and public investment in haemophilia care and areas like gene therapy research should make it a fully manageable, even curable, condition. But for the moment optimising the use of the range of blood factor replacement products available is the only viable way forward. One problem to be overcome is the development of inhibitors. These are antibodies which impair the actions of such treatments in about a third of all those receiving them for Haemophilia A, and in around 3 per cent of patients with severe to moderate Haemophilia B.

At one stage there were fears that switching between different products in the pursuit of cost savings could, along with individual genetic and variables and differences in treatment durations, drive inhibitor expression. This risk has now in large part been discounted, and the use of immune tolerance therapies (ITTs) can limit the harm caused to most individuals. But when the precise immunological mechanisms responsible for the development of inhibitors have been elucidated and if further protective actions are identified purchasing processes should seek to ensure good access to optimally effective treatment regimens.

- *Modern commissioning and procurement processes⁹ should foster positive provider and end-point user partnerships, focused on enhancing individual care standards*

There is now good evidence that personalised approaches to haemophilia care can generate better outcomes than less tailored ones. One way to enhance capacities to define and deliver good quality care is through – in appropriately regulated circumstances – pharmaceutical companies responsible for developing innovations working in partnership with clinicians to optimise treatment practices. This has in the case of UK Haemophilia Centre services in the past in part been achieved by, for instance, companies contributing to the funding of the Haemtrack service – which provides patients with a convenient way of recording bleeds and other unwanted events alongside treatment information – and to the employment of specialist nurses.

Such activities can complement charitable initiatives funded by 'third sector' organisations and may be seen as in line with the spirit of the 2014 European Procurement Directive. There is good reason to believe that if efforts to improve the treatment and support available to people living with haemophilia are made in a consistently principled manner (see Box 6) further health gains and socio-economic benefits will transpire. Yet some industry critics say that all drug prices should be stripped down to the minimum viable level, and that if the NHS wishes to commission any additional services these should be explicitly purchased.

In economic terms the justification for such parsimony is partly that it would avoid distortions associated with cross-subsidisation. But its advocates could be in danger of ignoring the fact that institutional and bureaucratic forces can sometimes oppose the introduction of new patterns of care for reasons that are not immediately commercial yet are nevertheless contrary to the public's best interests. Individuals working in specialised areas might on occasions fear that as and when economies are made in their fields 'gain share' hopes (to the effect that savings in pharmaceutical and allied costs will in part be returned to the teams and service areas achieving lower spending) will not materialise, and their capacity to win additional resources for 'their patients' will be permanently reduced.

In addition, 'social market' theorists may argue that prohibiting medicine or other product and service makers from being actively involved in developing the settings in which the potential benefits of the goods they supply are translated into reality could be detrimental to patient and

⁹ Procurement may be regarded as a policy neutral process that is separate from commissioning on the one hand and clinical practice and service provision on the other. However, the view taken here is that a broader definition of procurement ought to accept that a degree of overlap exists between these fields.

Box 6. 'Tender Loving Care' Principles

The survival and quality of life experienced by children and adults living with haemophilia has been radically transformed by the improving use of established and new pharmaceutical products. Amongst those with severe disease average life expectancy in the UK has increased from around 10 years in the 1950s to over 70 today, despite the impact of HIV. However, there is still considerably more that could be done to reduce disability and distress experienced by individuals and families living with haemophilia, and ultimately – through interventions like gene therapies – to cure the conditions involved.

Further long term investment in fundamental biopharmaceutical/biomedical research and development will be vital for achieving this last objective. But more immediately progress in generating better outcomes for people with bleeding disorders of all types could, as organisations like the UK's Haemophilia Society have helped to highlight, result from continuing to apply the principles underlying high quality health and social care delivery in increasingly rigorous and effective ways. (See, for example, Shire, 2016.) In relation to haemophilia these can be summarised as:

- **recognising and effectively meeting the need for personalised health care involving extended access to pharmacokinetic testing, more tailored dosing regimens and detailed personal care planning at every life stage.** It is important to note, for instance, that underlying rates of blood Factor breakdown can vary fourfold between individuals, and that differences in physical activity rates can also impact on bleeding risks;

- **promoting confidence in the availability of and belief in the value of good quality care amongst all service users, health professionals and others stakeholder groups.** Clinician trust and involvement is vital for the promotion of cost effective medicines prescribing, while enhancing patient motivation is often central to using pharmaceuticals to best effect;

- **recognising the full value of treatment improvements.** This relates critically to issues such as implementing MEAT based tendering in a constructive manner;

- **continuously improving outcome and related data collection.** Without this it will be difficult to improve therapeutic strategies in sensitive and appropriate ways, and to understand in depth the benefits that changes in care delivery can generate; and

- **ensuring value for money for the NHS in ways that will foster further industrial and professional success.** The pursuit of improved care quality without due regard to assuring well-evaluated cost effectiveness would be unsustainable. However, so too could be pursuing service savings in ways that undermine the ability pharmaceutical companies and/or the professionals with whom they work to fund innovation and seek in co-operation with other stakeholders to attain outcomes most desired by service users and their wider communities.

public interests in ways that will be difficult to identify until after they have negatively impacted on people's well-being. Aspects of this debate are touched on again later in this report. However, before that two other specialised medicines procurement areas are briefly explored. The first relates to the acquisition of treatments for infections such as HIV and Hepatitis C. The second is that of anti-cancer drug supply, which is set to be an increasingly important field in the coming decade as progressively more effective therapeutic regimens become available.

Protecting population-wide interests and maximising the wellbeing of individuals with HIV

It is now known that people were suffering from HIV/AIDS in regions such as the Congo in the early decades of the twentieth century and in all probability on a sporadic basis before then. But it was not until Africa opened up to the outside world that the infection was able to spread from rural villages and relatively isolated

cities such as the Kinshasa of the early 1900s to other world regions. AIDS was first recognised in the US and Europe at the start of the 1980s. For example, the radical social theorist and critic of modern psychiatric medicine, Michel Foucault, died of it in 1984, the year after pharmaceutical companies began work on producing recombinant Factor VIII.

There was originally no treatment available other than palliative care for what was at that time in practical terms a universally lethal condition. Although initially seen as primarily a threat to gay men, fears soon emerged that it could rapidly be transmitted to a large proportion of the sexually active population. In the UK this elicited a powerful public health protection response led by Margaret Thatcher's then Health Secretary, Sir Norman Fowler. There was also a wave of both private industrial and public investment in attempts to develop effective pharmaceutical treatments. Following the initial introduction of Zidovudine/AZT as an HIV treatment at the end of 1980s the NHS prioritised the supply of effective HIV therapies to all patients in need of them.

Despite total therapeutic costs of at one stage in the order of £10,000 per person per year, HIV/AIDS medicines have during the last 20 years been swiftly and comprehensively provided via the specialised NHS services established to treat people affected by the condition. Their appropriate use has not only protected individuals living with the virus, but has also helped to prevent its transmission to others. Notwithstanding concerns that some people with HIV have moved to this country from regions such as Africa in the hope of receiving better care than would otherwise have been available to them, the result of this strategy is that in the UK today there are only about 100,000 individuals living with the infection (National Aids Trust, 2016).

This is a very much lower relative burden of disease than that carried in countries that in the past took a less supportive approach to the care of individuals and populations at risk of HIV infection, including both the US and the Russian Federation. A substantial proportion of UK HIV patients live in cities like London and Brighton. Services in such locations are unsurprisingly high spenders on antiviral treatments, a fact which can be taken to underline the need for centrally allocated specialist service funding.

The life expectancy of people living with HIV, provided they are able to take the medicines prescribed for them as recommended, is now comparable to that of other healthy members of the community of a similar age. However, as HIV infection has shifted from being perceived as an acute threat to life to being a chronic condition that demands long term management tighter controls on treatment expenditures have been introduced.

Specialist HIV centres have in recent years operated with a ceiling on average per capita drug costs. The current figure stands at about £6,000 per patient per annum. It is also of note that NHS England has recently questioned its ability and/or duty to supply at public cost preventive drugs (as opposed to barrier based protectives) designed to stop individuals normally seen as having voluntarily put themselves at raised risk of exposure to HIV from contracting the infection. One NHS England spokesperson was recently reported to have said that if the NHS was 'forced' to pay for an expensive (circa £5,000 per annum) medicine for people who cannot or will not protect themselves from HIV it could lead to children with cystic fibrosis being denied effective new treatments.

From a populist standpoint such concerns may well be seen as appropriate in the current economic and social climate. Yet at the same time such positions to a degree parallel the approach of some Eastern European and other similarly minded policy makers in past decades. They may by a proportion of NHS doctors and other UK observers be regarded as a step away from the

successful British public health strategies established during the Thatcher administration. They might also be seen as exemplifying the direction that the unchecked pursuit of narrowly defined 'economy' could in future take the health service in England.

As with the haemophilia treatments discussed above, the procurement strategy which has to date allowed the UK to supply HIV treatment more cost effectively than many other developed countries has been based on informed clinician involvement and respect for their clinical judgement. Through this, Framework Agreements with manufacturers have been enabled to function effectively. Patients with special needs have access to higher cost medicines, while physicians elect to prescribe lower cost treatments as and when these can meet patients' needs. Such observations carry important lessons for the future of all forms of specialised care and treatment procurement.

Treating Hepatitis C

As with HIV infection, Hepatitis C is a condition for which no form of vaccine yet exists. Again as with HIV, various viral strains exist and not all are equally amenable to treatment. Until recently the available drugs were not only costly but of limited effectiveness. However, with the launch of medicines such as Sofosbuvir in 2014 and subsequently other antiviral products with different modes of action, it is now possible to deliver 95 per cent plus cure rates in settings like the UK.

There are estimated to be over 200,000 people living with Hepatitis C in this country (Public Health England, 2015). The majority are symptom free, and a relatively large percentage of individuals carrying the virus are undiagnosed. Despite the efforts of organisations such as the Hepatitis C Trust, case finding has not to date received high priority attention. From an NHS perspective this may be linked to the fact that only a limited proportion of chronically infected patients suffer significant levels of liver and related harm, and that today treatment in the later stages of the disease is likely – at least in physiological if not psychological terms – to be more or less as beneficial as early stage intervention.

It is in addition the case that the new drugs now on the world market are expensive as compared with products like widely used antibiotics. However, because of their curative efficacy NICE has found them to be cost effective in a range of contexts. This may have led to some tensions with NHS England, which is responsible for purchasing Hepatitis C therapies via the funds in its specialised care budget. It can be argued that just because an innovative medicine is both clinically effective and cost effective according to NICE's calculations, this should not necessarily be taken to mean that it is affordable when large volumes of the treatments involved are being demanded.

Part of the concern surrounding Hepatitis C medicines pricing¹⁰ and costs relates to unresolved questions about how many people with the infection should receive treatment at what stage in their illness, given the levels of experienced distress and the potential costs and benefits involved. Notwithstanding NICE's recommendations, NHS England's current strategy involves spending £190 million on antiviral medicines licensed for the treatment of Hepatitis C in 2016-2017, with the specialised centres responsible for providing care being limited to treating a total of just over 10,000 patients in the current year. These figures imply an average drug cost of a little under £20,000 per person accessing therapy, and a 'drug price' of approaching £21,000 per cure achieved.

Advocates for people with Hepatitis C may question the legality as well as the humanity of putting a cap on the number of patients to be treated, as might some pharmaceutical interests. However, against their concerns it can be argued that it represents a reasonable response to a highly unusual situation. For the purposes of this analysis key points to emphasise again relate to the importance of maintaining clinician involvement in and support for procurement strategies based on 'volume and cost based' Framework Agreements with a range of product suppliers.

It is also worth reiterating the fact that well designed tendering processes can achieve significant cost reductions even in fields where the treatments available have intellectual property protection attached to them, provided there is competition between alternative novel therapies. From a public interest perspective this is desirable, provided that savings are not generated at an unacceptable cost to further innovation and individual care standards. Public approaches to the purchasing of all forms of good and service should be sensitive to their overall value to society, not just their price.

Cancer medicines costs and benefits

In Britain anticancer drug pricing and access has been the most controversial of all medicines supply areas. This is to a degree reflected in the fact that although UK public and charitable contributions to cancer research are on a per capita basis amongst the highest in the world, NHS spending on such products has tended to lag behind that recorded in other similarly wealthy nations (Jonsson et al, 2016). Recent public debate has focused on issues ranging from the supply of Trastuzumab to women with early stage breast cancer through to the working and

future role of the Cancer Drugs Fund set up by the Cameron/Clegg coalition government in 2010.

The CDF has recently transitioned from being a special purchasing fund in England for buying treatments regarded by NICE as non-cost effective towards being a resource for facilitating the entry of anticancer drugs which are of initially uncertain cost effectiveness into NHS use. Between its establishment in 2010/11 and the decision to reform it in 2015 its cost rose from £200 million to in the order of £400 million a year, including overspend. (The budgeted figure was £340 million in 2015 – NHS England Cancer Drugs Team, 2016). This is a large percentage increase, albeit in absolute terms it is no more than the additional sums reportedly spent by the NHS on off-patent medicines which were until recently available as branded products but are now supplied on an exclusive (ie non-competitive) basis as much higher cost generic products. Because of this change some older exclusively produced treatments are no longer subject to effective NHS cost control, albeit new arrangements are now being introduced.

Cancer treatment is a complex field, covering many different diseases and multiple therapeutic modalities. However, from an overall medicines procurement perspective it is of note that despite the expenditure increases of the last few years anticancer medicine outlays in this country are still no more than average in European terms. They in total (including all outlays) account for about 10 per cent of medicines spending in England, or circa £1,500 million annually (Macmillan, 2015).

This is a substantial sum. Yet it represents little more than 1 per cent of gross health service costs or 0.1 per cent of the present GDP. Alarmist claims that the costs of anticancer medicines are unaffordable should therefore be avoided, especially given the reality that once more effective treatments have become established their costs will in time fall because of patent and other intellectual property expiries and enhanced production efficiency.

NHS England will in all probability continue to exert strong downward pressure on anticancer medicine costs. In a period in which public spending as a whole could face increasing curbs this could well be judged necessary by many observers. However, as the work of the Accelerated Access Review might help to highlight, undue restrictions on the amount that the health service is prepared to pay for innovative treatments could disadvantage some patient groups. Less importantly from a humanitarian viewpoint, it might also harm UK based industry. In the 'post Brexit' environment this country has important strategic interests in remaining at the front of biomedical research and product development.

At this point in history the scientific and financial investments made in cancer research and treatment

¹⁰ In the US these have reportedly been in the order of \$80-100 thousand per patient treated. However, true outlays are often lower due to the effects of discounting driven by competitive pressures and expert procurement practices. In poorer countries such as India and Egypt (where rates of Hepatitis C infection are very high as a result of anti-schistosomiasis programmes that in previous decades spread the infection via contaminated needles) courses of sofosbuvir are available for under 1 per cent of the US list price.

throughout the twentieth century are beginning to make significant differences to patient survival. However, failures to ensure that NHS users gain timely access to advances in cancer treatment could, as in other areas of therapeutic advance such as the care of individuals and families affected by rare diseases, in time undermine confidence in the health service. Achieving excellence in drug procurement could well prove an important means of avoiding such unwanted outcomes.

Optimising NHS Medicines Procurement

When, in the aftermath of World War II, the NHS was first established it was the first major tax funded universal health care system. The primary intention of the experts responsible for its planning during the time of the coalition headed by Winston Churchill and the voters who elected the subsequent Labour administration led by Clement Atlee was not to create the world's most cost effective health care system. It was rather to create the best affordable one for everyone in the country.

In a number of important respects this promise has been delivered. Yet there is some evidence – particularly if the provision of health related social care is added into the equation – that because of the centrality of taxation as opposed to insurance raised finances to the NHS model eventually accepted by Aneurin Bevan and his colleagues, the UK has been less willing to fund adequate health and social service levels than countries such as The Netherlands, France and Germany.

The extent to which such criticisms can with validity be made in the case of medicines supply is debatable. Notwithstanding the special concerns that exist in oncology, the access of people in England and the rest of the UK to evidence based pharmaceutical care has generally been good, even compared to that observable in North America and the richer EU Member States. In the specific context of specialised medicines procurement facilitated via tendering in fields like that of haemophilia care there is reason to believe that NHS purchasing practices have in the main been as, or more, advanced as any others to be found across the world.

Yet this is not to say that all patient needs have been met as well as they could have been, or that further improvements in individually oriented care are not possible. Nor is to deny that in the years to come there are dangers that the situation could deteriorate, unless hazards are clearly signposted and action is taken to avoid them. Seeking the lowest possible pharmaceutical prices without due regard for total value is one such problem. Failing to provide optimally effective treatment to all in need would be another.

On the basis of the literature review and interviews undertaken to support the preparation of this report, the view taken here is that the most effective way to defend against unwanted trends and build constructively on what has to date been achieved is to retain an explicit public policy focus on counter-balancing the potential ill-effects of unchecked monopsonistic (single buyer) medicines purchasing powers. The need to be careful with public money should be set alongside a defined commitment to defending national (and world-wide) public interests in incentivising research and development in the biopharmaceutical and related fields and creating environments which encourage innovative approaches to clinical care delivery.

Regardless of how in detail relevant lines are drawn, it has been a long standing strength of the PPRS that its stated purpose has not simply been to minimise pharmaceutical prices and costs. It is also charged with protecting public interests in innovation and industrial success. Arguably, similar principles should also be clearly embedded in all NHS procurement activities, whether or not these are led by NHS England or those private procurement agencies that might in future work on its behalf or by NHS pharmacists and other health professionals with regional or local Trust based roles.

In addition, the recognition given by the 2014 EU Procurement Directive to the importance of forming Innovation Partnerships in areas where unmet needs exist deserves attention – see Box 7. Innovative medicines should not be seen as simple context-free commodities. They are better regarded as complex service linked products that need to be used in well-informed and constantly improving ways. Dynamic partnerships between their producers and users help achieve this end. There is therefore a risk that impersonal purchasing relationships which discount the value of inputs by pharmaceutical or other manufacturers into health care quality and outcome improvement initiatives would prove counter-productive.

A second strength of the traditional NHS approach to specialist medicines procurement as exemplified in fields like the treatment of people with haemophilia has been the involvement of clinicians in decision making relating to their practice fields and in the implementation of agreed policies. In future there should be opportunities to add further value via, for instance, enabling Clinical Reference Groups and patient organisations to extend their 'higher level' inputs into identifying unmet health needs and new therapeutic improvement options. Yet care should be taken not to permit any further drift towards centralisation to undermine awareness of the vital role that local clinician and service user 'policy concordance' plays. Without this it would be impossible for Multi-supplier Framework Agreements to work as well as possible, and to deliver efficiency gains in ways

consistent with the exercise of informed choice by patients and their individual doctors.

Increasing the extent to which service users and their representatives are effectively involved in guiding medicines (and other) procurement processes¹¹ would also be consistent with the stated aims and objectives of the AAR. Patient centred caring practices structured in ways which seek to resolve the problems that humanity faces in an equitable and rational manner are clearly desirable. Further developing them should help keep this country at the leading edge of health care provision and new treatment development, even if exit from Europe were eventually to undermine other aspects of the British life sciences base.

Recognising value generation

Other examples of ways in which NHS medicines procurement might in future be further improved range from ensuring that the principle of local 'gain sharing' is firmly embedded in the use of tendering mechanisms through to effectively adopting MEAT (Most Economically Advantageous Tender) based purchasing strategies. In the case of gain sharing, for example, if clinician support for actions which reduce costs at the possible expense of support for service improvements is to be maximised then some local apportionment of the savings achieved is likely to be required. If this common sense view is accepted then the key policy options to be resolved relate to the extent to which active partnerships between external companies and NHS organisations such as specialist care centres add value in ways which bureaucratically controlled funding transfers cannot achieve with similar levels of creative efficiency.

With regard to MEAT based tendering, it similarly makes sense to seek to try to include all aspects of value generation and consumer gain in purchasing decision making. However, this is easier said than achieved. A key finding offered here is that despite recognition of the fact that price minimisation alone is not the objective of high quality procurement, day to day pressures will often mean that in practice – unless effective systemic safeguards are put in place – price will swamp other considerations. While rhetorical respect for the importance of all quality dimensions may be prevalent, inadequately managed and monitored approaches to medicines procurement could in reality foster a 'cheapness at any cost' ethos.

Further research is needed to determine the magnitude of such risks, and the ways in which they can most appropriately be mitigated. However, one way forward might, as discussed in Box 7, be to create a low cost but robust system that will permit NHS pharmaceutical and allied product suppliers to apply for their status as NHS

Innovation Partners to be assessed by an independent body. Once awarded, such rankings could – with other relevant variables – be used in an agreed manner to moderate procurement decisions. Such a measure would not, of course, resolve all concerns and possible disputes. But it could help to ensure that the spirit of the European procurement approach now embodied in this country's legislation is tangibly expressed.

Conclusion

Efficiency gains bring benefits in every sphere of life. Yet they may also generate unwanted consequences, unless well-structured efforts are made to avoid or minimise such costs. In the modern world, in which the accelerated working of nation-wide and global markets supported by technical advances like computerised information systems is putting increasing downward pressures on the prices of many products, there is a need to balance the advantages of intensified competition generated via enhanced procurement practices with the need to ensure that valued aspects of goods and services, and with them on occasions entire ways of life, are not lost in the pursuit of financial savings.

Good procurement strategies help control spending, drive growth and increase prosperity. However, in fields such as purchasing medicines and using them as wisely as possible to promote individual and public health the application of commercial values and techniques should be tempered by professionalism, and a comprehensive and compassionate concern for the care needs of individuals and the well-being of entire communities.

Pharmaceutical suppliers should be exposed to robust scrutiny and testing competition. But their products ought also to be obtained in ways consistent with public interests in fairness towards intellectual property holders and ongoing private and public investment in innovation. Patients with unmet therapeutic needs presently stand to gain from fundamental progress in areas such as genetics and the application of advances in the biopharmaceutical and biomedical sciences to the treatment of their conditions. They can also benefit from developments in the ways that existing products are used to optimise health outcomes. Research based pharmaceutical companies have roles to play in both these areas.

The NHS is already one of the world's most advanced pharmaceutical purchasers. The available evidence shows that its procurement skills, used in ways consistent with current British and European law, have – against the background provided by factors such as the working of the PPRS and NICE's interventions – kept overall spending on medicines and allied products expressed as a percentage of GDP below the OECD average.

¹¹ That is by being able to exercise active choice, rather than simply advising others who are in control of decision making.

Box 7. Recognising NHS Improvement Partners

In the 2014 Procurement Directive the concept of Improvement Partnerships primarily relates to private product providers working with public purchasing organisations to develop innovations designed to fill identified gaps in the market. But in the health sector it might also usefully be applied to agencies like pharmaceutical companies working with specialist – and other – health service providers in order to optimise the use of existing technologies and improve health outcomes.

In the haemophilia context, for instance, there is evidence that company support for information gathering via Haemtrack (see, for instance, <http://haemtrack.mdsas.com/>) and the employment of specialist nurses has contributed to better service provision. In future it could add further to care quality by improving access to pharmacokinetic (PK) testing and other core elements of personalised treatment provision.

As discussed in the main text, some critics argue that health service commissioners alone should be in direct control of all aspects of NHS development. They may say that if external companies can afford to support service improvements it is evidence that they are charging too much for their goods or services, and that they are only investing such funds in order to generate more earnings. The counter argument to this is that in properly working free markets such activities benefit consumers. The appropriately expanded use of tailored therapies should enhance outcomes, while closer working between industry and NHS based professionals could also benefit new product research and service delivery.

From a public interest perspective the most important questions in this debate are about whether it is likely to be more efficient to work further towards giving NHS commissioners total control of all health related resources, or if maintaining a degree of ‘social market’ flexibility in which clinicians and pharmaceutical companies can use marginal resources to institute practice innovations and on occasions challenge bureaucratic service planners would advantage patients and the wider community. The view taken here is that the case for the latter interpretation is stronger than is likely to be recognised by observers located within the established health service command chain.

There can of course be no magic solutions to the challenges inherent in seeking to maintain well-balanced NHS purchasing strategies. But if it is accepted that ‘*product plus service support*’ offers have the potential to be more efficient than alternative options one way forward could be to grant research based companies which offer both innovative products and resources for developing new treatment approaches the status of ‘NHS Improvement Partners’. Such awards could be approved in a light touch manner by an independent regulatory or monitoring agency. One of the possible uses of this would be to help ensure that in MEAT based purchasing an agreed value is given to positive contributions to pharmaceutical and wider health care development. This could reduce the danger of contracting for sophisticated items like medicines being reduced to simplistic commodity assessments and a lowest possible price buying ethos.

Likewise, despite some access concerns in areas like oncology and the treatment of rare diseases, the record of the NHS in providing good quality pharmaceutical care to those in need of it is good in international terms.

Nevertheless, in the period leading up to Britain’s exit from the European Union the health service could well, along with other public services, have to face new pressures. There is a risk that this will create a situation in which procurement processes will become unduly focused on minimising prices and immediate spending, rather than seeking maximum longer term advantage. At worst this will alienate NHS users and the wider public, and may in some contexts threaten the sustainable supply of medicines. It might also stand in the way of forming and maintaining the close partnerships between research oriented companies and health care providers that this country needs to further enhance its health and wealth.

There is no guaranteed way of promoting a healthy balance between pursuing the affordability of pharmaceuticals and protecting public interests in

innovation and industrial success. Constructive progress will require insight and good-will on all sides. But the concluding recommendation offered here is that British policy makers should seek to ensure that the strategic thinking underlying the MEAT approach outlined in the revised 2014 European Public Procurement Directive remains central to the future tendering based methods employed in the NHS. Otherwise the approach that will evolve could, contrary to the spirit presently underpinning NICE’s existence and the working of the PPRS as well as long term public interests, come to focus exclusively on minimising the prices of items purchased at the expense of quality and ongoing innovation.

References

- ABPI, 2016. *UK Medicines Spend*. London: ABPI
- Association of Colleges (2016). *Why is Procurement Important?* <http://www.felp.ac.uk/taxonomy/term/671> (last accessed August 2016)
- Cabinet Office (2015) *2010 to 2015 Government Policy: Government Spending. Policy Paper*. <https://www.gov.uk/government/publications/2010-to-2015-government-policy-government-spending> (Last accessed August 2016)
- Department of Health (May 2012). *NHS Procurement: Raising our Game*. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216538/dh_134498.pdf (Last accessed August 2016).
- Department of Health (February 2016) *Operational productivity and performance in English NHS acute hospitals: Unwarranted variations*. An independent report for the Department of Health by Lord Carter of Coles
- European Commission (2014). *Public Procurement in a Nutshell*. http://ec.europa.eu/trade/policy/accessing-markets/public-procurement/index_en.htm (Last accessed August 2016)
- Eurostat 2016. *Gross Domestic Expenditure on R&D (GERD)*. http://ec.europa.eu/eurostat/web/products-datasets/-/t2020_20 (Last accessed August 2016)
- HM Treasury (2013, annexes revised August 2015). *Managing Public Money*. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/454191/Managing_Public_Money_AA_v2_-_jan15.pdf (Last accessed August 2016)
- Jonsson B., Hofmarcher T., Lindgren P. and Wilking, N. (2016). *Comparator report on patient access to cancer medicines in Europe revisited*. IHE report 2016:4. Lund: Institute for Health Economics
- Kenny T (2016). Personal communication
- Macmillan (2015) *About the Cancer Drugs Fund* (revised July 2015) <http://www.nhs.uk/ipgmedia/National/Macmillan%20Cancer%20Support/assets/TheCancerDrugsFundMCS5pages.pdf> (Last accessed August 2016)
- National Aids Trust (2016). *People Living with HIV in the UK*. <http://www.nat.org.uk/HIV-in-the-UK/HIV-Statistics/Latest-> (Last accessed August 2016)
- NHS England (2014). *The Review of Specialist Pharmacy Services in England*. <http://www.medicinesresources.nhs.uk/en/Medicines-Awareness/Policy/Policy/Pharmacists-The-Review-of-Specialist-Pharmacy-Services-in-England/> (Last accessed August 2016)
- OECD (2015). *Health at a Glance, 2015*. http://www.oecd-ilibrary.org/content/book/health_glance-2015-en (Last accessed August 2016)
- Office of Fair Trading (2007). *The Pharmaceutical Price Regulation Scheme: An OFT Market Study* <http://webarchive.nationalarchives.gov.uk/20140402142426/http://www.oft.gov.uk/OFTwork/markets-work/pprs> (Last accessed 17th August 2016)
- O'Mahony B, Noone D and Prihodova L. (2015) Survey of Coagulation Factor Concentrates Tender and Procurement Procedures in 38 European Countries. *Haemophilia* 21: 436-443
- NHS England Cancer Drugs Fund Team (July 2016) *Appraisal and Funding of Cancer Drugs from July 2016 (including the new Cancer Drugs Fund)*. <https://www.england.nhs.uk/wp-content/uploads/2013/04/cdf-sop.pdf> (Last accessed 17th August 2016)
- Public Health England (2015) *Hepatitis C in the UK: 2015 Report*. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/448710/NEW_FINAL_HCV_2015_IN_THE_UK_REPORT_28072015_v2.pdf
- Shire (2016). *Delivering Value in Haemophilia Discussion Paper*. Basingstoke: Shire Pharmaceuticals
- Taylor D. G. and Maynard A (1990). *Medicines, the NHS and Europe*. London: King's Fund Institute



This LSE Report was written by Andrew Bonser, Panos Kanavos and David Taylor. Andrew Bonser is an independent health sector consultant specialising in pharmaceutical affairs and Professor Panos Kanavos is the Deputy Director of LSE Health. David Taylor is UCL Emeritus Professor of Pharmaceutical and Public Health Policy and is editorially accountable for the content of this document.

This report was commissioned and funded by Shire plc.
Full editorial control rested with the LSE authors.



Copyright © London School of Economics, October 2016

DOI No. 10.21953/LSE.RO.67824 (<http://dx.doi.org/10.21953/LSE.RO.67824>)

Design & print: www.intertype.co.uk