A new value-based approach to the pricing of branded medicines

A consultation
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A consultation on proposals for a new value-based system of pricing medicines which aims to recognise and reward innovation. The document sets out the principles that would underpin the move to value-based pricing, outlines how the new system could work across the UK and seeks views on a number of key issues.

Responses are invited to this consultation by 17 March 2011

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Ministerial Foreword

Medicines can transform people’s lives and add enormously to life expectancy. Ensuring that medicines make the greatest possible contribution to people’s health is a key objective for this Government. This is why, in The Coalition: our programme for government, we said we would introduce a system of value-based pricing so that patients can access the medicines and treatments their doctors think they need.

The current system of pricing medicines has tried to achieve a balance between reasonable prices for the NHS and a fair return for the industry to develop new medicines. However, it does not promote innovation or access in the way this Government is looking for. Also, too often, the NHS has been in the position of either having to pay high prices that are not always justified by the benefits of a new medicine, or having to restrict access.

We are determined to create a system that gives patients access to the most effective medicines. There must be a much closer link between the price the NHS pays and the value that a medicine delivers. Pharmaceutical companies need a pricing system that is more stable and transparent, and that gives clear signals about priority areas, so that research efforts are directed to greatest effect. It is important that there is a common pricing policy across the United Kingdom. However, the Devolved Administrations determine many aspects of health policies including those affecting the use and availability of medicines within their health systems. This consultation document outlines a new system which aims to recognise and reward innovation, in particular by encouraging a focus towards genuine breakthrough drugs which address areas of significant unmet need.

We will build on our strengths: NICE is a world-leader in its field, and it will continue to have a central role, both in undertaking pharmaco-economic assessments and in providing advice to the NHS on the relative clinical and cost effectiveness of treatments.

This UK consultation provides an important opportunity for different groups to give us their views on how we should reflect the value of medicines and design a system that delivers the best health outcomes for the people of the UK. We look forward to your responses.

[Signature]

Secretary of State for Health
1. Introduction

1.1 In common with many countries, the prices of medicines are regulated in the UK. As set out in the coalition agreement,¹ the Government intends to introduce a new system of value-based pricing by reforming arrangements for the pricing of branded medicines. The Government intends to move to this system when the current Pharmaceutical Price Regulation Scheme (PPRS) expires at the end of 2013.

1.2 The purpose of value-based pricing is to improve NHS patients’ access to effective and innovative drugs by ensuring they are available at a price that reflects the value they bring. It will give patients and clinicians greater access to medicines, based on an assessment of the outcomes that they can achieve.

1.3 The Government's long-term vision for the future of the NHS in England was set out in the NHS White Paper, “Equity and Excellence: Liberating the NHS”². It sets out how the NHS will put patients first, focus on outcomes and empower clinicians. Medicines have an important role to play in delivering this vision.

1.4 This document sets out the principles that would underpin the move to value-based pricing, outlines how the new system could work across the UK and seeks views on a number of key issues. The consultation will run for 13 weeks from 16 December 2010 to 17 March 2011. Based on the responses to this public consultation, we will actively engage key stakeholders in developing the new system.

¹ The Coalition: our programme for government
² Equity and excellence: Liberating the NHS
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2. Context and case for change

2.1 The Government believes that there are significant shortcomings in the current system for branded drug pricing and access. The Coalition: our programme for government outlined the Government’s commitment to move to a system of value-based pricing for medicines so that patients can access the drugs and treatments doctors think that they need. Moving to a valued-based system should provide NHS patients with better access to effective and innovative medicines at a price that secures value for the NHS. The Government will work towards the introduction of the new arrangements on expiry of the current PPRS agreement at the end of 2013.

2.2 The Coalition: our programme for government also confirmed the Government’s commitment to the establishment of a Cancer Drugs Fund in England from April 2011. The Fund will address some of the most pressing access issues, enabling cancer patients to be treated with the cancer drugs their doctors think will help them. It will begin to make the connection to a value-based approach by putting clinicians and cancer specialists in the driving seat to decide how the funding is best spent for patients. The Fund will bridge the gap until the introduction of new medicines pricing arrangements, which would then formalise the relationship between value and price. Both the Cancer Drugs Fund and value-based pricing reflect the Government’s determination to give more power to clinicians to take decisions about treatments in collaboration with patients.

The current pricing system

2.3 In the UK, prices of branded prescription medicines are regulated by the Pharmaceutical Price Regulation Scheme (PPRS). The PPRS has existed since 1957 and is usually renegotiated every five years. It is a voluntary scheme agreed between the Department of Health and the branded pharmaceutical industry. It is underpinned by statutory powers.

2.4 The PPRS has sought to achieve a balance between reasonable prices for the NHS and a fair return for the industry to enable it to research, develop and market new and improved medicines. Under the PPRS, pharmaceutical companies have freedom of pricing for new active substances. However, the PPRS controls the prices of branded medicines through regulating the profits that pharmaceutical companies are allowed to make on their sales to the NHS.

Health Technology Assessment and the role of NICE

2.5 The National Institute for Health and Clinical Excellence (NICE) is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health. This includes providing recommendations to the NHS on the use of new and existing medicines and treatments. NICE has a well-deserved

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3 The 2009 Pharmaceutical Price Regulation Scheme
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reputation as an international leader in its field, and it plays a pivotal role in ensuring patient access to clinically and cost effective drugs and treatments.

2.6 NICE’s guidance on specific new drugs and treatments is based on a review of clinical and economic evidence, assessed through the technology appraisal process. The purpose of a technology appraisal is to provide clear recommendations to the NHS on the circumstances in which the use of a drug is both clinically and cost effective. The NHS in England is legally obliged to fund medicines and treatments recommended by NICE’s technology appraisals.

2.7 The Devolved Administrations have their own arrangements for Health Technology Assessment and for assessing the extent to which NICE’s technology appraisal guidance should be adopted. For example, the Scottish Medicines Consortium provides advice to the NHS in Scotland on the clinical and cost effectiveness of all new licensed drugs, and advice on the applicability of NICE’s Multiple Technology Appraisal guidance is provided by NHS Quality Improvement Scotland (QIS).

2.8 NICE does not have a role in relation to the pricing of medicines, though the scrutiny of its appraisal process may encourage drug companies to set prices which satisfy its cost-effectiveness criteria. However, if NICE concludes that a drug may offer some benefits but that these are not sufficient to justify the price at which the drug is available, NICE’s only option is to recommend that the NHS restricts its use of that drug. There is no scope for NICE in England, or its parallel bodies in the rest of the UK, to enter into pricing negotiations or to recommend an NHS price.

Introducing greater flexibility in the PPRS

2.9 The 2009 PPRS introduced more flexible pricing options which enable drug companies to improve the value specific drugs offer to the NHS. This was, in part, in response to a recommendation by the Office of Fair Trading in their 2007 market study of the PPRS.4

2.10 Patient Access Schemes, which offer discounts or rebates to reduce the cost of a drug to the NHS, have played an important role in helping more patients to access drugs that would not otherwise have been assessed as cost-effective by NICE or the SMC. In England for example, Patient Access Schemes have helped to make a number of drugs available to patients including Lucentis for the treatment of macular degeneration, Sutent for renal cell carcinoma and gastrointestinal stromal tumour and Velcade for multiple myeloma.

2.11 In addition, NICE has introduced new flexibilities in its appraisal of drugs for less common, end of life conditions to improve access to these drugs. However, there remain drugs which NICE has not felt able to recommend even with the application of a more flexible approach to decision-making, and which drug companies have been unwilling or unable to price at a level NICE would regard as cost-effective.

4 The Pharmaceutical Price Regulation Scheme: an OFT market study
The bio-pharmaceutical industry

2.12 The UK is home to a world class pharmaceutical industry that has seen a fifth of the top 75 selling medicines discovered here. The UK has consistently punched above its weight when attracting investment from the bio-pharmaceutical industry. We are only 3% of the global market but we receive around 9% of global investment from the industry. Our economy benefits with around 70,000 jobs and £4 billion invested in research each year.

2.13 We want the UK to be an environment that encourages innovation and where the NHS is a world leader in carrying out clinical trials. We have asked the Academy of Medical Sciences to undertake an independent review to bring forward recommendations for simplification of medical research regulation and governance which will improve the time it takes for the NHS to set up clinical trials. This will help attract industry investment in the UK and support the Government’s aim to grow the economy. Industry tells us that it can take between 10 to 15 years to bring an innovative drug to market, and due to the regulatory requirements and high attrition rate, this can cost in the region of £500-800 million.

The case for change

2.14 The PPRS has provided some stability over time, but it does not promote innovation or access in the way we are looking for. In particular, freedom of pricing for new drugs puts the NHS in the position of either having to pay high prices that are not always justified by the benefits of a new drug, or having to restrict access.

2.15 Initiatives like Patient Access Schemes and the Cancer Drugs Fund are helping to make more drugs that can benefit NHS patients available, but these are not long-term solutions. For example, the cumulative administrative burden falling on front-line NHS staff from Patient Access Schemes must be managed. So the Government believes that more needs to be done. There must be a much closer link between the price the NHS pays and the value that a medicine delivers. The Government is determined to create a system that gives patients access to the most effective medicines. If companies decline to supply a medicine at a price that relates to its value, it will be their responsibility to explain why.

2.16 Pharmaceutical companies also need a pricing system that is more stable and transparent, and that gives clear signals about priority areas, so that research efforts are directed to maximum effect. We need a system which can recognise and reward innovation, in particular by encouraging a focus towards breakthrough drugs which address areas of significant unmet need.

2.17 We also need a better way of dealing with new drugs whose benefits are more limited. For example, product-line extensions, which are comparable to, or offer only small benefits over existing treatments may not add much for patients. The NHS should not have to choose between paying over the odds or restricting access.

2.18 NICE is a world leader in pharmaco-economic evaluation of drugs, and should continue to fulfil its vital role as a centre of excellence and provider of authoritative advice and information to the NHS. This is of course only one aspect of NICE’s overall remit: our
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NHS White Paper for England, *Liberating the NHS*, signalled a significant future expansion of NICE’s work on the development of authoritative quality standards for health and social care, along with tools and guidance to support commissioners in delivering them. NICE quality standards will set out each part of the patient pathway, along with indicators for each step. Subject to Parliamentary approval, NICE itself will be re-established in the forthcoming Health & Social Care Bill, to guarantee its status and ensure it is fit for purpose.

2.19 There will continue to be a role for technology appraisals, which measure the health benefits and costs of a new product and compare them with the costs and health benefits that could be gained if the funds were used elsewhere in the NHS. But the current approach may not adequately reflect all the components that contribute to a treatment’s full impact on health and quality of life. And it may not always be apparent how important factors that patients and society value, such as impacts on carers, are taken into account. This could be reflected more systematically and transparently in assessments of new medicines.
3. Objectives of the value-based pricing approach

3.1 As noted above, the pricing system for new medicines needs to address a number of important objectives. It must strike a balance between delivering reasonable prices for the NHS and ensuring that industry is incentivised to undertake research, develop and market new and improved medicines. This has been the main focus of the current PPRS.

3.2 However, it is important to encourage innovation in areas of greatest unmet needs and to help to ensure patients can access new medicines that may benefit them. These goals are not adequately addressed in the current system.

3.3 Value-based pricing therefore aims to address a broader set of objectives than the current system. It should:

- improve outcomes for patients through better access to effective medicines;
- stimulate innovation and the development of high value treatments;
- improve the process for assessing new medicines, ensuring transparent, predictable and timely decision-making;
- include a wide assessment, alongside clinical effectiveness, of the range of factors through which medicines deliver benefits for patients and society;
- ensure value for money and best use of NHS resources.

3.4 The new system must also be stable and sustainable over the longer term, so that industry is able to plan and prioritise research in areas which can deliver the greatest potential benefits to patients and society.

- Are the objectives for the pricing of medicines set out in this document – better patient outcomes, greater innovation, a broader and more transparent assessment and better value for money for the NHS – the right ones?
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4. Outline of the proposed system

Scope

4.1 Value-based pricing will be at the core of the new system for regulating the prices of branded medicines, which will succeed the current PPRS at the end of 2013. It is the Government’s intention that value-based pricing will apply to new active substances placed on the market from 1 January 2014. Subject to discussion with industry, some existing medicines could be included within the value-based pricing system. Like the PPRS, we expect the value-based pricing arrangements to apply to branded, and not generic, medicines.

4.2 As it would not be feasible to carry out a value-based pricing assessment for each individual branded medicine that is already available, our intention is that branded medicines that are on the market prior to 1 January 2014 would be covered by new arrangements sitting alongside value-based pricing.

4.3 For branded medicines already covered by PPRS at the end of 2013, a successor scheme to the PPRS will be required. The details of this will be developed alongside value-based pricing. Following the outcome of this consultation and in line with longstanding practice in this area, the Department of Health will engage with relevant representatives of the pharmaceutical industry on the details of these arrangements.

4.4 As we develop and refine the value-based pricing model, we will pay particular, careful attention to the potential impact on special groups of medicines. It may be appropriate to apply slightly different arrangements to some medicines, as is the case now. For example, some drugs that treat very rare conditions are currently funded through the arrangements for the national commissioning of specialised services. However, the presumption will be towards designing the system in a way that minimises the need for parallel mechanisms.

- Should value-based pricing apply to any medicines that are already on the UK market before 1 January 2014? If yes, should this be determined on an individual basis, or are there particular groups of drugs which might be considered?

- Are there types or groups of medicines, for example, those that treat very rare conditions, which would be better dealt with through separate arrangements outside value-based pricing?

Key elements of the value-based pricing model

4.5 The key principle of value-based pricing is to ensure NHS funds are used to gain the greatest possible value for patients. So the Government would set a range of thresholds or maximum prices reflecting the different values that medicines offer.

4.6 The value of new products would be assessed and their benefits compared with the benefits that could be gained if the funds required were used to help patients elsewhere...
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in the NHS. This comparison is normally expressed with a cost-effectiveness threshold. It requires the use of a “common currency” for quantifying benefits in a consistent and comparable way across the full range of health-related conditions.

4.7 One (but not the only) option would be to use Quality Adjusted Life Years (QALYs), the ‘currency’ currently used by NICE in its technology appraisals. A QALY is the amount of health represented by a year of life at full health. It gives an idea of how much extra length of life and the quality of life a person might gain as a result of treatment – and health gains from different treatments can be expressed in terms of the number of QALYs to which they are equivalent. If we used the QALY in value-based pricing, the threshold would be expressed as a cost per QALY gained.

4.8 In the existing system, a standard cost effectiveness threshold is applied to all new products, with some flexibility to take account of additional relevant factors, including societal preferences. However, the mechanism for taking wider factors into account is not completely transparent, and this may lead to perceptions that important factors are not adequately reflected in the assessment process.

4.9 By contrast, under the new system of value-based pricing, the Government would apply weightings to the benefits provided by new medicines, which would imply a range of price thresholds reflecting the maximum we are prepared to pay for medicines. These thresholds or maximum prices would be explicitly adjusted to reflect a broader range of relevant factors so they could be used to calculate the full value of a new product.

4.10 The Government proposes that the price threshold structure is determined as follows:

i. there would be a basic threshold, reflecting the benefits displaced elsewhere in the NHS when funds are allocated to new medicines;

ii. there would be higher thresholds for medicines that tackle diseases where there is greater “burden of illness”: the more the medicine is focused on diseases with unmet need or which are particularly severe, the higher the threshold;

iii. there would be higher thresholds for medicines that can demonstrate greater therapeutic innovation and improvements compared with other products;

iv. there would be higher thresholds for medicines that can demonstrate wider societal benefits.

4.11 Designing the new system to be both stable and transparent would allow companies to predict well in advance how prospective products may fare, and to focus their research efforts on the treatments that society values most. Companies would be informed of these weightings – allowing them to orient their research and development investments appropriately.

4.12 In introducing this system, the Government would move away from a system of negotiations once every five years under the PPRS to a more stable framework. This greater predictability and transparency will give companies greater certainty for making long term investment decisions.

i) The “basic” cost-effectiveness threshold
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4.13 As part of value-based pricing there would be a basic cost effectiveness threshold, directly reflecting the health gains displaced when new treatments are funded. This would set the maximum that the Government was prepared to pay for medicines that offered no additional value in terms of innovation, tackling diseases with a high burden of illness or wider societal benefits.

4.14 The basic threshold need not be the one currently used by NICE. In developing value-based pricing, there would be a re-evaluation of the “basic” cost-effectiveness threshold, to put estimates of the value of alternative uses of NHS funds on a sound, evidence-based footing. This should ensure that the threshold is fit for purpose in the new system. Work is already in hand with external experts to achieve this.5

ii) Adjusting the threshold to reflect “Burden of Illness”

4.15 Under the current system, while treatments are assessed using the estimated total health benefits they provide, there is limited flexibility to recognise that society may place a greater weight on treating particularly severe and life-threatening conditions. The current system may not fully reflect society’s preferences if there are no existing alternative treatments, and so a significant unmet need. In addition, it may not always be apparent how the flexibilities that do exist in the current system take such concerns into account.

4.16 Under value-based pricing, there would be higher thresholds for diseases with higher “Burden of Illness”. The most important factors contributing to the measurement of “Burden of Illness” would be the severity of the condition and the level of unmet need.

4.17 Severity could reflect the health status without the new treatment, and also if the condition leads to premature death or serious morbidity. It could be assessed in terms of the existing QALY unit of health benefit – which can be used to quantify the outstanding health loss.

4.18 Unmet need could reflect the degree to which there are existing treatments. A condition for which there is no effective treatment, and where there is, therefore, significant unmet need, could be characterised by a high QALY loss, and deemed to exhibit a high “Burden of Illness”. Conversely, conditions that were already well served with effective treatments would be scored at a lower level on this measure – even if the untreated condition was itself severe and life-threatening.

4.19 Unmet need could be calculated for different indications for the same medicine. So there could be different maximum prices or thresholds for the same medicine depending on the indication. This would enable greater sensitivity of pricing for value but it would be a far more complex system and there could be significant practical issues in implementing such an approach.

4.20 Higher thresholds or maximum prices would create an appropriately increased reward for new treatments, which tackle diseases where existing treatments still leave patients

5 Ref: "Methods to estimate the NICE cost-effectiveness threshold" - MRC Research Grant to Professor Mark Sculpher, University of York. [http://www.mrc.ac.uk/ResearchPortfolio/Grant/Record.htm?GrantRef=G0901498&Caseld=15883](http://www.mrc.ac.uk/ResearchPortfolio/Grant/Record.htm?GrantRef=G0901498&Caseld=15883)
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facing severe and life-threatening illness, compared to those diseases that are already comparatively well served with current treatments. The scale of the adjustment would need to reflect an assessment of the evidence for society’s priorities in treating serious and life-threatening conditions.

- Do you agree that we should be willing to pay more for medicines in therapeutic areas with the highest unmet needs, and so pay less for medicines which treat diseases that are less severe and / or where other treatments are already available?

- How should we approach the issue of a single drug which delivers significantly different benefits in different indications?

- What steps could be taken to address the practical issues associated with operating more than one price for a drug, if we took such an approach?

iii) Adjusting the threshold to reflect “Therapeutic Innovation and Improvement” of products

4.21 Under the current system, treatments are fundamentally valued in proportion to the amount of additional benefit they provide to patients. However, this may lead companies to focus on incremental improvements that can be easily made, and not to make the significant investments required to achieve breakthroughs in performance through innovation.

4.22 Incremental improvements can be important. For example, reductions in side effects, especially where these are serious, can mean that more patients are able to benefit from a treatment. However, a new version of an existing medicine is not necessarily an improvement on its predecessor, and patients may gain little from a range of medicines whose benefits are essentially the same.

4.23 Under value–based pricing, higher thresholds or maximum prices would reflect the scale of the “Therapeutic Innovation and Improvement” achieved by individual products. Therapeutic innovation and improvement would be assessed by whether a new medicine represented a significant improvement relative to existing treatments. It would reflect any additional health gain not captured by the normal pharmaco-economic assessment of the health gain because of measurement difficulties.

4.24 “Therapeutic Innovation and Improvement” weightings could be expressed using the existing QALY units for health benefit. A treatment representing a significant breakthrough and an important advance over existing therapies would provide a large QALY benefit – and achieve a commensurately high “Therapeutic Innovation and Improvement” score. It could also be represented by a qualitative assessment of the innovation reported by a new medicine reflecting e.g. new modes of action.

4.25 The scale of the adjustment for differing levels of improvement would be designed in order to give an appropriately increased incentive to companies to focus their resources on achieving genuine step changes in clinical performance, rather than seeking just to make incremental changes. The scale of the adjustment would need to reflect the evidence for the effects of pricing incentives on company R&D investment, and the consequent impact in achieving significant clinical breakthroughs. By including
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weightings for unmet need in burden of illness combined with therapeutic innovation and improvement there should be a substantial incentive towards medicines that represent a step change in benefits for patients and away from drugs that cannot demonstrate such clear benefits.

- Do you agree that – compared to the current situation – we should be willing to pay an extra premium to incentivise the development of innovative medicines that deliver step changes in benefits to patients but pay less for less innovative drugs?

- In what ways can we distinguish between levels of innovation?

iv) Pharmaco-economic evaluation

4.26 The pharmaco-economic evaluation would be similar to the technology appraisal process currently carried out by NICE. It would calculate the patient health benefits of the product and reflect all costs and benefits beyond the direct purchase price of the medicine – including, for instance, cost savings elsewhere in the treatment pathway.

4.27 Medicines can have benefits for society that go beyond pure health benefits, for example they can have impacts on time spent with carers. The current system does not explicitly adjust for some of these societal benefits. Our aim is for the scope of pharmaco-economic evaluation in value-based pricing to be enlarged to more explicitly reflect impacts of a product beyond direct health effects. These might include benefits related to reduced reliance on carers, and other wider societal factors, so that the value of a new medicine is captured through its impact on all dimensions of health related quality and quantity of life that are important to society.

v) The price mechanism

4.28 Based on the output of the full assessment of value of a product, expressed as a weighted cost per QALY (or alternative measure) the threshold or maximum price would be determined.

vi) Setting thresholds

4.29 As set out above, in looking at new medicines, we currently assess their benefits and use a cost-effectiveness threshold to compare these with the benefits displaced elsewhere in the NHS if the new treatment is adopted. In value-based pricing, we are proposing that the value society gains from a treatment could be reflected by adjusting the basic cost-effectiveness threshold, in order to reflect the additional aspects of benefit described above. It should be noted that this approach could be seen as a comparable alternative to applying weightings to the health benefits gained from treatments, and comparing them to a standard NHS cost-effectiveness threshold.

4.30 The setting of the thresholds will be key to ensuring that the new system delivers better access, incentivises more innovative medicines and remains affordable. The Government will undertake substantial modelling to ensure that the final system meets these objectives.
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4.31 The burden of illness and therapeutic innovation and improvement categories, which will govern the weightings to be applied, will be decided by the Secretary of State for Health on the basis of expert advice, within an overall framework that will be determined in advance. One important aspect to be determined is how many different categories, and therefore, how many different possible weights (and thus price ranges) there will be.

4.32 For example, “burden of illness” could be separated into different indications. A smaller number of categories implies a simpler system, but may risk masking important distinctions, for example, within a particular patient population. However, having too many categories would risk jeopardising our objective of a transparent and predictable system. The Government could pre-populate the burden of illness category or set out criteria for determining the burden of illness and allow companies to put forward evidence to support the classification of a particular indication.

- How can we best derive the weights that will be attached to each element of the assessment? Are there particular elements we should put greater weight on?
- What measure should we use to define the weightings? Options might include using the existing Quality Adjusted Life Years (QALY) measure, patient experience and expert opinions or some combination of these.
- How can we best derive the different categories for burden of illness and therapeutic innovation and improvement?

Patient Access Schemes in value-based pricing

4.33 Patient Access Schemes, as discussed above, were introduced with the aim of enabling NHS patients to access cost-effective innovative medicines. Increasing patient access to effective innovative medicines at a price that secures value for the NHS lies at the heart of our plans for value-based pricing. So we would not anticipate the need to continue the 2009 PPRS Patient Access Scheme arrangements for new medicines assessed under value-based pricing.
5. How the system will operate

5.1 Within an overall framework covering medicines pricing in the UK, the Government would determine the baseline cost-effectiveness threshold, the scope of pharmaco-economic evaluation including wider factors and the weightings for burden of illness and therapeutic innovation and improvement. These weightings would determine the thresholds and would be transparent. The exact construction of the thresholds for the value-based pricing system would be evidence based, reflecting the views of experts.

5.2 Burden of illness weightings, including severity and degree of unmet need could be published in advance; to do so would send important signals concerning priorities for innovation. It would, however, also impose a considerable burden. Alternatively, Ministers, with the support of expert panels, could set a framework and companies could come forward with evidence of unmet need and severity within this.

5.3 For individual new medicines, companies will have to produce a set of data. NICE (with bodies responsible for technology appraisal in the Devolved Administrations) would provide advice to Ministers and the manufacturer on the costs and benefits and health gain attributable to that product. NICE will be the key source of advice on the relative cost-effectiveness of new medicines, although in future this will be combined with other aspects of value before a reimbursement price is determined. Given the expertise of NICE, they will play an important role in any new system, but the details of their role will depend on, amongst other things, the responses to this consultation.

5.4 More generally NICE’s role will increasingly focus on giving authoritative advice to clinicians on when and how the most effective treatments can best be used and on the development of quality standards which set out the standards the NHS should aim for in the treatment of certain conditions. The assessment of relative clinical and cost effectiveness of treatment options will play a continuing part in the development of NICE clinical guidelines.

5.5 The manufacturer would have freedom to propose a price for a new medicine and provided this translated into a figure equal to or less than the basic cost effectiveness threshold, that price would be accepted for the NHS. If, however, the manufacturer considered that a higher price was warranted, they would need to provide robust evidence demonstrating that the new medicine merited a higher weighting in terms of burden of illness, therapeutic innovation and improvement, or clinical and wider societal benefits.

5.6 Alongside the pharmaco-economic evaluation and within the value-based pricing assessment, expert panels would review the evidence produced by the company and determine the relevant categories in terms of burden of illness, therapeutic innovation and improvement and wider societal benefit for a new medicine. This would determine what, if any, weightings would be applied to arrive at a threshold or maximum price for that drug.

5.7 If the company’s price was higher than that justified by the value-based pricing assessment, the Government would ask the company to lower their price, or produce further verifiable evidence to justify its claim about the value of the new medicine. If the
company were not prepared to do either of these, it would be the company’s responsibility to explain to the public why it was not prepared to offer that drug at an appropriate price.

5.8 The value-based pricing model will be based on a robust assessment of the evidence relating to a new medicines’ value to patients and society. However, there may be cases where there is insufficient evidence to support the value-based pricing assessment of a new medicine. For example, for some medicines, long-term data will be needed to demonstrate relative performance with complete confidence and such data may not be available at the time a product comes to market. One approach might be to set a price that is supported by the evidence available at launch, but to allow prices to be adjusted as better evidence becomes available.

- What approach should be taken under value-based pricing where insufficient evidence is available to allow a full assessment of the value of a new medicine?

5.9 The speed of assessment and agreeing prices for new medicines is important. The process should be set up in a way that enables a robust evaluation of the value of new medicines, without being excessively burdensome or bureaucratic. It will also be important to ensure that appropriate mechanisms are in place for resolving any divergence of views about the assessed value of a new drug. However, a slow process could delay access to new medicines for UK patients. The Government is proposing that companies could make drugs available at a contingent price, which will subsequently be adjusted to reflect evidence of effectiveness.

- Does the system set out above describe the best combination of rapid access to prices and affordability?

5.10 It is likely that, over time, circumstances will arise which warrant review of a value-based pricing assessment. For example, a medicine may initially be used to treat one condition and later gain licences in other areas, and the burden of illness weighting may differ for the different indications. The level of therapeutic innovation and improvement may also change, in particular, as experience is gained of how a medicine performs in real clinical practice as compared to clinical trials.

- In what circumstances should a value-based pricing assessment be subject to review?

Value-based pricing and the new commissioning arrangements

5.11 For GP consortia in England, value-based pricing offers the opportunity of increasing access to medicines. GPs should have clinical freedom to determine their patient’s needs, or to commission through consortia for the more flexible use of drugs in secondary care (where the strains in the current system are most commonly felt). They can be confident that, at a time when consortia have increasing responsibility for NHS resources, the drugs their patients receive reflect value for money. They, and the commissioning organisation, should no longer be in the invidious position of having to balance limited clinical benefit on the one hand, with disproportionate cost, and opportunity cost, on the other. This approach reflects the Government’s view that
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doctors are best placed to make clinical decisions, whilst being supported in their prescribing and commissioning roles by consortia and, importantly, by authoritative and expert advice from NICE.

5.12 For companies, the new pricing scheme, NICE’s role in supporting best clinical practice and the requirement for GP consortia to be held to account for outcomes, should provide a strong incentive to supply new medicines to the UK.
6. Transition arrangements

6.1 Value-based pricing will not be introduced until 2014. The Government recognises the value that the pharmaceutical industry places on the stability and predictability that the PPRS brings. That is why we have confirmed that we will honour the terms of the current PPRS agreement in full. Alongside this, existing arrangements for evaluating new drugs will remain in place until the introduction of value-based pricing in 2014.

Pricing flexibilities

6.2 In line with the commitment to honour the current agreement, the pricing flexibilities, including Patient Access Schemes, which were introduced in the 2009 PPRS, will remain in place, and companies will continue to have the option of making proposals under these arrangements until the expiry of the current agreement.

6.3 It is important that we ensure that the cumulative administrative burden for the NHS arising from Patient Access Schemes remains manageable. Under the terms of the 2009 PPRS, a review of pricing flexibilities is due to be initiated by the end of 2010.

6.4 Transitional arrangements for operational Patient Access Schemes will need to be considered in the context of the wider arrangements that will succeed the PPRS for branded medicines not subject to value-based pricing – that is, those already on the UK market at 1 January 2014. However, in the first instance, we would expect pharmaceutical companies to continue to honour their commitments to make agreed Patient Access Schemes available on a continuing basis until review of the relevant NICE guidance.

Cancer Drugs Fund in England

6.5 Alongside Patient Access Schemes, the Cancer Drugs Fund offers an interim mechanism in England through which patients can receive drugs that would not otherwise be funded under current arrangements. As set out above, the Cancer Drugs Fund is a 3-year interim arrangement aimed at bridging the gap until the introduction of value-based pricing in 2014.

6.6 On 27 October, the Government launched The Cancer Drugs Fund: a consultation. The consultation, which runs until 19 January 2011, invites views on how we can ensure the Fund meets its objectives as well as possible. The Cancer Drugs Fund consultation notes that, as part of the transition to a new medicines pricing approach, consideration will need to be given to the position of drugs that have been funded through the Cancer Drugs Fund following a negative NICE appraisal.

6.7 The Government’s objective will be to ensure that patients who have received drugs through the Cancer Drugs Fund and who have a continuing need for those drugs can continue to receive them. We will also want to determine suitable arrangements under which patients who may in the future benefit from receiving such drugs can do so, at a
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cost that represents value to the NHS. The Cancer Drugs Fund consultation invites views on how this might best be achieved.\footnote{Cancer Drugs Fund - a consultation (closes for comments 19 January 2011)}

- What arrangements could be put in place within the new medicines pricing system to facilitate access for patients who may benefit from drugs previously funded through the Cancer Drugs Fund, at a cost that represents value to the NHS?

The role of NICE and the SMC in the interim period

6.8 NICE’s role in ensuring patient access to clinically and cost effective drugs and treatments remains critical. NICE will continue to appraise new drugs until we implement our plans for value-based pricing from 2014, and, as set out above they will have an important part to play in these longer-term plans.

6.9 We envisage that under a value-based pricing system medicines will be made available to patients if their clinicians recommend them. But until we are assured that the improvements in access to medicines we want to see are realised, we will continue to ensure that the NHS in England funds drugs that have been positively appraised by NICE.
7. Conclusion

7.1 Our approach to paying for new medicines has far-reaching implications. It is easy to think of this just in terms of the healthcare that patients receive through the NHS. However, this would be to ignore wider social and economic considerations, such as the important role played by the pharmaceutical industry in the UK economy. We need to work closely with the pharmaceutical industry as any system that they opposed would not deliver benefits to UK patients. It is therefore important that, in designing a new system, we give due consideration to the range of relevant factors and ensure that these are appropriately reflected in the new model.

7.2 The principle of linking the price of new medicines to their value has already received support from a broad range of stakeholders. The complexity inevitably lies in determining how ‘value’ is defined and measured. The approach set out above includes broad scope to consider the full range of relevant factors when assessing value, including health and wider benefits, addressing unmet need and stimulating innovation. However, there are limits to the number of factors which can meaningfully be addressed. In addition, there may be some considerations which do not apply to all medicines. For example, growing antimicrobial resistance means that there is a high need for new antibiotics, but that these should only be used sparingly.

- Will the approach outlined in this document achieve the proposed objectives of better patient outcomes, greater innovation, a broader and more transparent assessment and better value for money for the NHS?

- Are there other factors not mentioned in this document which the new system should take into account?

7.3 A key objective of value-based pricing is to change the incentives within the medicines pricing system, to encourage the development of new medicines in areas of greatest unmet need, and to promote genuine innovation. New medicines that deliver significant improvements in performance in the treatment of severe illness where current treatments are lacking will be advantaged under the new system. However, in the context of limited overall resources, a realignment of incentives means that some medicines will do less well, and would warrant a lower price, than they might achieve under current arrangements.

7.4 It is important to be clear that value-based pricing is not as simple as achieving the lowest price possible. Such an approach would risk disincentivising investment in research, with the potential consequence that patients would not benefit from innovative new treatments. We need to strike a balance between the value we realise now and the investment we are willing to make to stimulate future benefits.

7.5 It is more important than ever that we are sure that we are achieving the best possible value for every penny of taxpayers’ money that we spend. This is as true for NHS spend on pharmaceuticals as for every other area of public expenditure. So the prices we pay for drugs must be commensurate with their benefits.
7.6 The move to a value-based pricing system will represent a significant change from the current approach to the pricing of new medicines, albeit that some elements of the system, e.g. a role for NICE, are likely to be familiar. In implementing such a major change, it is likely that we will encounter some obstacles, challenges and unintended consequences.

- Are there any risks which might arise as a result of adopting the value-based pricing model as outlined above? If so, how might we try to reduce them?
- What steps could be taken to ensure that value-based pricing has a positive impact in terms of promoting equalities?
- Are there any other comments or information you wish to share?
Summary of consultation questions

- Are the objectives for the pricing of medicines set out in Section 3 of this document – better patient outcomes, greater innovation, a broader and more transparent assessment and better value for money for the NHS – the right ones?

- Should value-based pricing apply to any medicines that are already on the UK market before 1 January 2014? If yes, should this be determined on an individual basis, or are there particular groups of drugs which might be considered?

- Are there types or groups of medicines, for example, those that treat very rare conditions, which would be better dealt with through separate arrangements outside value-based pricing?

- Do you agree that we should be willing to pay more for medicines in therapeutic areas with the highest unmet needs, and so pay less for medicines which treat diseases that are less severe and/or where other treatments are already available?

- How should we approach the issue of a single drug which delivers significantly different benefits in different indications?

- What steps could be taken to address the practical issues associated with operating more than one price for a drug, if we took such an approach?

- Do you agree that – compared to the current situation – we should be willing to pay an extra premium to incentivise the development of innovative medicines that deliver step changes in benefits to patients but pay less for less innovative drugs?

- In what ways can we distinguish between levels of innovation?

- How can we best derive the weights that will be attached to each element of the assessment? Are there particular elements we should put greater weight on?

- What measure should we use to define the weightings? Options might include using the existing Quality Adjusted Life Years (QALY) measure, patient experience and expert opinions or some combination of these.

- How can we best derive the different categories for burden of illness and therapeutic innovation and improvement?

- What approach should be taken under value-based pricing where insufficient evidence is available to allow a full assessment of the value of a new medicine?

- Does the system set out above describe the best combination of rapid access to prices and affordability?

- In what circumstances should a value-based pricing assessment be subject to review?
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- What arrangements could be put in place within the new medicines pricing system to facilitate access for patients who may benefit from drugs previously funded through the Cancer Drugs Fund, at a cost that represents value to the NHS?

- Will the approach outlined in this document achieve the proposed objectives of better patient outcomes, greater innovation, a broader and more transparent assessment and better value for money for the NHS?

- Are there other factors not mentioned in this document which the new system should take into account?

- Are there any risks which might arise as a result of adopting the value-based pricing model as outlined above? If so, how might we try to reduce them?

- What steps could be taken to ensure that value-based pricing has a positive impact in terms of promoting equalities?

- Are there any other comments or information you wish to share?
Annex A – Glossary

**Branded drug** – a drug that is sold under a brand (or proprietary) name, rather than its generic name, e.g. Nurofen (generic name: ibuprofen), Avastin (generic name: bevacizumab)

**Burden of illness** – made up of factors including the severity of a condition and whether there are any existing treatments

**Cancer Drugs Fund** – a fund which the Government plans to put in place from April 2011, designed to improve patient access to cancer drugs until a reformed model of drug pricing is put in place in 2014. The Cancer Drugs Fund proposals are currently under public consultation until 19 January 2011 and an Interim Fund of £50m is in place until April 2011

**Devolved Administrations** – the Scottish Government, the Welsh Assembly Government and the Northern Ireland Executive

**Devolved Nations** – Scotland, Wales and Northern Ireland

**Gastrointestinal stromal tumour** – a tumour of connective tissue in the stomach, small intestine, or other part of the intestinal tract

**GP consortia** – groups of GP practices, who will be responsible for commissioning the majority of healthcare services required by their local population

**Health Technology Assessment** – a process for determining the clinical and cost effectiveness of a particular health technology (drugs, medical devices (such as artificial hip joints), diagnostic techniques, surgical procedures and other treatments to improve health or prevent ill health)

**Indication** – the use of a certain treatment for a particular condition

**Macular degeneration** – a medical condition which causes a loss of vision in the centre of the eye from damage to the retina, usually affecting older people

**Multiple myeloma** – a cancer of the plasma cells

**NICE (National Institute for Health and Clinical Excellence)** – the independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health

**National Specialised Commissioning** – commissioning carried out at a national level for certain highly specialised services which are high cost, low volume interventions and treatments. Examples include: heart and lung transplants and highly specialised mental health services for young people.
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Patient Access Schemes – schemes which can be proposed by pharmaceutical companies when drugs are undergoing a technology appraisal. They aim to make a specific drug or technology more cost-effective and allow more patients to gain access to the drug through mechanisms such as discounts to the list price, or rebate schemes.

Patient pathway – a multidisciplinary tool for managing quality in healthcare, promoting organized and efficient patient care based on evidence based practice.

PPRS (Pharmaceutical Price Regulation Scheme) – a voluntary agreement between the Department of Health (on behalf of the UK health departments) and the branded pharmaceutical industry (represented by the Association of the British Pharmaceutical Industry) which aims to ensure that the NHS has access to good quality branded medicines at reasonable prices, and promotes a healthy, competitive pharmaceutical industry.

Pharmaco-economic evaluation – an economic evaluation is used to compare the costs and benefits of a healthcare intervention to assess whether it is worth doing. The aim of an economic evaluation is to maximise the level of benefits - health effects - relative to the resources available. It should be used to inform and support the decision-making process; it is not supposed to replace the judgement of healthcare professionals.

QALY (Quality Adjusted Life Years) – a measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health.

Quality standards – a set of specific, concise statements produced by NICE that act as markers of high-quality, cost-effective patient care, covering the treatment and prevention of different diseases and conditions.

Renal cell carcinoma – a type of kidney cancer.

Scottish Medicines Consortium – advises NHS bodies in Scotland about the status of new medicines.

Technology Appraisal – the process which NICE use to determine the clinical and cost effectiveness of a health technology (drugs, medical devices (such as artificial hip joints), diagnostic techniques, surgical procedures and other treatments to improve health or prevent ill health).

Therapeutic Innovation and Improvement – assessed by whether a new medicine represents a significant improvement compared with existing treatments, or where the new treatment is a significant breakthrough, such as a new mode of action.
Annex B – The consultation process

You can respond to the consultation by either completing the response form available from http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_122760 and emailing to: valuebasedpricing@dh.gsi.gov.uk

or by posting it to:

Value Based Pricing,
Helena Bowden - Consultation Coordinator,
Department of Health,
Skipton House
80 London Road
London
SE1 6LH

Comments should be received by 17 March 2011.

Criteria for consultation

This consultation follows the ‘Government Code of Practice’, in particular we aim to:

• formally consult at a stage where there is scope to influence the policy outcome;
• consult for at least 12 weeks with consideration given to longer timescales where feasible and sensible;
• be clear about the consultation’s process in the consultation documents, what is being proposed, the scope to influence and the expected costs and benefits of the proposals;
• ensure the consultation exercise is designed to be accessible to, and clearly targeted at, those people it is intended to reach;
• keep the burden of consultation to a minimum to ensure consultations are effective and to obtain consultees’ ‘buy-in’ to the process;
• analyse responses carefully and give clear feedback to participants following the consultation;
• ensure officials running consultations are guided in how to run an effective consultation exercise and share what they learn from the experience.

The full text of the code of practice is on the Better Regulation website at: Link to consultation Code of Practice

Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact Consultations Coordinator
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Department of Health
3E48, Quarry House
Leeds
LS2 7UE

e-mail consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter.

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and, in most circumstances, this will mean that your personal data will not be disclosed to third parties.

Summary of the consultation

A summary of the response to this consultation will be made available before or alongside any further action, such as laying legislation before Parliament, and will be placed on the Consultations website at http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/index.htm