Department of Health consultation on a new value-based approach to the pricing of branded medicines

1. I write with regard to the Department of Health consultation on a new value-based approach to the pricing of branded medicines.

2. The Royal College of General Practitioners is the largest membership organisation in the United Kingdom solely for GPs. Founded in 1952, it has over 42,000 members who are committed to improving patient care, developing their own skills and promoting general practice as a discipline. We are an independent professional body with enormous expertise in patient–centred generalist clinical care. Through our General Practice Foundation, established by the RCGP in 2009, we maintain close links with other professionals working in General Practice, such as practice managers, nurses and physician assistants.

3. The College welcomes the opportunity to respond to this consultation. We note the objectives that the Department of Health states as guiding the proposed changes:

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

To ensure value for money and best use of NHS resources.

4. The College believes these objectives are laudable and is confident that our members will support them in principle.

5. We agree that the case for value-based pricing as set out here is well-made and attractive in many ways. It may well lead to pricing for many products that is better aligned to products’ overall societal benefits. There are problems in some specifics, outlined below, and we are not confident that the current proposals will in practice achieve all of the objectives, but broadly we are supportive of the direction of travel.

6. However, in the context of the Government’s wider reforms of the NHS in England, we have very serious concerns about the proposal to remove from the National Institute for Health and Clinical Excellence (NICE) responsibility to provide definitive guidance to the NHS on the use of drugs and health technologies. Given the proposed role of GP consortia in commissioning local NHS services, we foresee the following detrimental effects:

i. In time, GP consortia (GPCC) may be placed under excessive pressure, for example from patient lobby groups, individuals, local elected representatives, pharmaceutical companies and press campaigns, to provide treatments contrary to NICE advice. Most GPCC will find it very difficult – given the lack of local expertise and resources to evaluate clinical effectiveness - to counteract this pressure, with the potential perverse outcome of prescribing driven by external pressure rather than clinical judgement.

ii. The argument about whether certain treatment options should be used is likely to exacerbate tensions between doctors in the primary and secondary/specialist care sectors. Where at present both consultants and GPs are aware of and bound by the same NICE guidance, under the proposed system a consultant may initiate a very expensive treatment, and it will be for the GP to confirm or refuse, potentially placing them in an invidious position with regards to the patient.

iii. Patients with the same condition, on the same ward, may be entitled to different treatments, given that the decision to prescribe will be dependent on the GP consortia rather on national guidelines or geographically based health service.
iv. Given the proposed abolition of practice boundaries and the right of all patients to register with GPs where they choose, as well as the ‘any willing provider’ proposal to encourage patients to choose their secondary care providers, there will be widespread ‘postcode lottery’ effects - it is likely that patients with conditions for which expensive treatments may be prescribed will ‘shop around’ – effectively becoming NHS tourists, moving from practice to practice and seeking providers from whom these treatments will be available. Not only will this generate instability for providers, but in the absence of firm guidance from NICE it is possible that this will inflate the overall drug budget.

v. For GPs a major concern is that this proposal will erode their relationship with their patients. GPs see their role as being the patient’s advocate, prescribing the best course of treatment for the individual’s healthcare needs. We are sure that this will continue to be the case, but worry that it may be open to public doubt when GPs, in their role as commissioners, are also responsible for the allocation of resources. A threat to the trust between doctor and patient, which may be magnified through its portrayal in the press, could have repercussions for the uptake of services and clinical interventions, and ultimately on perceptions of the NHS as a whole.

7. These comments reflect some of the major concerns in the College’s earlier responses to the Health White paper. We would strongly urge reconsideration of the proposed changes to the role of NICE. We do not see that these are integral to the proposals on value-based pricing, and might in fact have the effect of undermining some of the objectives of the proposals. It is not entirely clear from the context of the document (Chapter 5) precisely what status NICE assessments will have with regards to final price set – we would urge that this be re-framed to restore NICE’s fully authoritative role and avoid the dangerous consequences outlined above.

8. We have answered some of the specific consultation questions below:

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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? Yes, we agree with these objectives.

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? We would be interested to hear the Department of Health’s proposals for the pricing of existing medicines. To apply value-based pricing retrospectively would clearly be a major, labour-intensive and costly exercise. But there is need for a clear system to ensure a balance of pricing between old and new drugs – and to a degree any assessment of value-based pricing is incomplete without knowing the approach to older medicines.

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? We would agree that parallel or separate arrangements should be made for some specific medicines and conditions which the proposed criteria of value-based pricing might exclude. We would not wish to see patients with rare conditions excluded, or excessive burdens placed on those practices with which they are registered – so some specialised national commissioning would be necessary.

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? We agree that unmet need is a useful criterion. However there needs to be awareness of potential unintended consequences – for example that we might end up paying more for drugs that actually had relatively little development or manufacturing costs, simply because they meet a previously unmet need. Similarly, how would we deal with the case of an old drug (taking aspirin as an extreme example) that is found to have a new indication?

How should we approach the issue of a single drug which delivers significantly different benefits in different indications?
As stated in the document, there would be considerable difficulties in attempting to set multiple prices for indications for the same drug. Solutions to this, including allowing manufacturers to choose from a range of tariffs, are proposed in the CHE report on value based pricing\(^3\).

**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?**

No comment.

**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?**

We do agree with this pricing principle, though note that it is often initially difficult to identify the ‘step change’ medicines. The Department of Health should also consider reform in the constraints pharmaceutical companies have in bringing a drug to market, as it is these extraordinarily high costs that make companies reluctant to research in orphan areas, as well as increasing costs of medicines to the NHS.

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

Clearly this needs to be carefully enforced – many drugs are brought to the market with claims of significant innovation but in reality offer little benefit over existing medicines. Re-assessment of value based on evidence from use must be built into the system.

**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?**

No comment.

**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.**

No comment.

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

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\(^3\) Claxton K, Sculpher M, Carroll S, Value based pricing for pharmaceuticals: its role, specification and prospects in a newly devolved NHS, p6-8 (Centre for Health Economics 2011) - [http://www.york.ac.uk/media/che/documents/papers/researchpapers/CHERP60.pdf](http://www.york.ac.uk/media/che/documents/papers/researchpapers/CHERP60.pdf)
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?

We agree that it can often take a while to establish the true value of a new medicine, whilst it would not be desirable to hold a drug back for this reason, as this would potentially delay availability in the UK as against other countries. Prices would need to be re-assessed after a period of practical use. The prospect of re-assessment might also provide a stimulus to further research (see the CHE research paper on Value based pricing4). The document does not describe this process of re-assessment in any detail. Our respondents express concern that it may be more costly and bureaucratic than anticipated and need to cover a wider range of drugs – the example is given of dronedarone, where need to monitor liver function tests is now apparent; this was not the case at launch, and would have affected assessment of cost-effectiveness and value.

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

It seems a reasonable system – though we have concerns in practice over whether the process of negotiation with the drug companies might not delay access to innovative medicines.

Additionally, it is unclear what will happen if pharmaceutical companies refuse to meet the government’s price – the statement in the document ‘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’ (paragraph 5.7) is somewhat opaque. It appears to leave open the possibility that commissioners will be pressured to pay for medicines that the government has decided are too expensive. Alternatively, as the UK makes up only 3.5% of the global pharmaceutical market, it seems quite plausible that companies may refuse to cooperate in order to keep their prices high – with the result that more patients in the UK may lose out compared with those in other countries.

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

No comment

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?

We have expressed our views regarding the Cancer Drugs Fund in a previous consultation response. In our response we were critical of the proposal, arguing that cancer drugs should not be given priority over expensive drugs for other conditions, that the suggested benefits were overstated since cancer drugs are sometimes not as effective as claimed by manufacturers, and that NICE guidance should not be disregarded. We refer the reader to paragraph 6 of the present response for reasons why it is inadvisable to devolve responsibility for accepting or vetoing expensive medicines from NICE to local commissioners; all these reasons may be particularly pertinent in the phase of transition from the Cancer Drugs Fund to value-based pricing.

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?

Value-based pricing has the potential to achieve these objectives to some extent and is a reasonable proposal if implemented carefully. Our respondents worry that many of the new drugs produced in the next few years will qualify as ‘me-too’ drugs and therefore be outside the scope of these proposals. They also foresee that, whatever system is put in place, rising drug prices and new technologies in the years ahead will place the NHS under considerable pressure.

In this context, we argue that it is all the more undesirable to devolve what are effectively rationing decisions from NICE to GP consortia. This part of the proposals has the potential to thoroughly undermine the stated objectives – by exposing GPs to pressures from pharmaceutical companies, national press, local campaign groups and secondary care colleagues, the danger is that clinical judgement may be displaced, which can only have a negative impact on overall patient outcomes and value for money, whilst at the same time increasing unfairness through the ‘postcode lottery’ effect.

RCGP, Response to Department of Health Consultation on Cancer Drugs Fund (RCGP 2011)
Are there other factors not mentioned in this document which the new system should take into account?

We do not claim expertise in pharmaceutical economics; however we would be concerned that the document does not give sufficient attention to wider, even global economic factors. How will the proposed system adapt to changes in exchange rates and different pricing policies elsewhere (for example in the Euro-zone countries) which may make it more attractive to supply products to other markets?

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?

There are short-term risks of inappropriate prices being set through lack of evidence – as discussed already, these can be addressed through careful evidence-based reassessment. As discussed, far greater risks are created by the change in the status of NICE guidance.

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

The change of the role in NICE is likely to mean that the proposals will have a negative effect on equalities – by creating differences of treatment between areas (‘postcode lottery’) and between conditions (through media and campaign groups exerting pressure for some treatments and not others). This should be reconsidered.

It will also be important to ensure that the proposal to retain some national commissioning for specialised services for very rare conditions is followed through – not to do so might potentially leave patients with these conditions open to discrimination within the proposed new commissioning model.

In other respects, the proposals to place drug pricing on a rational footing weighted to broad societal priorities should promote equalities.

Are there any other comments or information you wish to share?

Please see paragraphs 6-7 above. We note also the roundtable discussion by the Kings Fund in January, which raised many further points. We feel that our members views are substantially reflected in this.
9. We gratefully acknowledge the contributions of members of the College’s Council in formulating this response

Yours sincerely

Professor Amanda Howe
Honorary Secretary of Council