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

Royal Pharmaceutical Society Response

The Royal Pharmaceutical Society (RPS) is the new professional body for every pharmacist in Great Britain. We are the only body that represents all sectors of pharmacy in Great Britain.

The RPS leads and supports the development of the pharmacy profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession’s policies and views to a range of external stakeholders in a number of different forums.

Its functions and services include:

**Leadership, representation and advocacy**: promoting the status of the pharmacy profession and ensuring that pharmacy’s voice is heard by governments, the media and the public.

**Professional development, education and support**: helping pharmacists to advance their careers through professional advancement, career advice and guidance on good practice.

**Professional networking and publications**: creating a series of communication channels to enable pharmacists to discuss areas of common interest.

The changes for the pharmacy profession, as suggested in this consultation are minimal with many current exemptions being retained.

**General comments**

Whilst we welcome the concept of Value Based Pricing (VBP), as a product being priced in line with its value can only be a good thing, we have concerns around how such a system would be implemented in practice. This consultation document does not present enough detail so we can only really offer commentary and identify specific gaps and issues. It appears that some parts of a proposed VBP system are valuable but there are still lots of unanswered questions.

We feel this consultation must be the first in an iterative process where the government will consult further, and engage more fully with all key stakeholders, as more details about this proposal emerge. We believe that the pharmacy profession is central to the development of VBP given its knowledge and expertise in the full cycle of the making and taking of medicines. We are keen to keep an open dialogue as the process is developed.

We do not believe, as stated in the consultation document, that a VBP system in the UK will determine the direction of innovation with the global pharmaceutical industry or that it will necessarily lead to better access to and choice of medicines for patients unless other countries adopt a similar approach.
Great Britain has a world-class reputation for science and innovation. Any proposed system of VBP must deliver a stable environment in which drug manufacturers can function. The consultation talks about continuing PPRS in some form and the ‘old’ PPRS will be in place for many years until all products can be reviewed. We will therefore have three systems operating at the same time, plus a different pricing system for generics. This presents the NHS with a new and complex pricing system at a time when there is already large scale organisational change.

The new system needs to be designed with consideration for the secondary care market where most of these high cost new medicines are likely to be used, rather than the primary care market where the current PPRS system appears to be more effective.

We do think that a VBP system could lead to a more transparent and honest system on pricing and that it could drive evidence of effectiveness for medicines i.e. evidence of outcomes. It could also lead to value for money for patients, purchasers and the industry and is an opportunity to deliver an approach that will deliver for the system and service needs. It could also enable an open debate about rationalisation and lead to an explicit understanding of what is valued and the price associated with such a value. It could lead to an improvement of existing systems if it captures additional societal benefits and could include patients needs throughout the decision making process. It could also ensure that medicines are seen as integral to the wider commissioning agenda rather than a separate consideration.

It is unclear from this consultation how the VBP system will work. There needs to be a clear understanding of who makes the decisions, where this sits in the overall system and the system must be completely transparent. Any decisions made on both value and price need to be robust enough to withstand a judicial review. The effect of referencing pricing also needs to be taken into consideration.

This consultation document does not consider how orphan drug legislation, which is set across the world, fits in with a VBP system. Also, it does not clarify whether or not the Pharmaceutical Price Regulation Scheme (PPRS) system will be completely abolished or if some medicines will continue to sit under an evolved PPRS system as VBP will only initially be considering new medicines. There is little clarity how an evolved PPRS system will work alongside a VBP system.

If we look at the concept of VBP there are several stages that require more thought and clarification:

**Determining value:**
It is not clear from the consultation how value will be determined and who will carry out this important role. We believe that the value of a medicine should also include societal benefits and should have a better appreciation of patient outcomes. The framework of ethical considerations is a good basis on which to consider the value of a medicine.

Service provision also has to be part of the evaluation of value i.e. will the new medicine lead to an increase in service or a decline in a current service? This may require some form of modelling if the information is not currently available.

If a medicine is not taken by a patient, or taken inaccurately, then it is of no value. Therefore, medicines adherence also needs to be part of the process when a value of a medicine is determined. This important aspect of medicines adherence needs to be recognised and secured; pharmacy

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obviously has a major role to play in this. Pharmacy also has a contribution to make in assessing how
the value of medicines actually turns out in practice as they are the front-line professionals who
interact very closely with medicine users.

It is not clear if medicines will be re-evaluated after a defined time period e.g. 3 years. If so, we
believe that Patient Reported Outcome Measures (PROMs) should be used as part of the
reassessment process to ensure patients’ views are included. Also, how can the cost-effectiveness,
value and price of a medicine be re-evaluated post licence if the way the medicine is used in clinical
practice bears no resemblance to the way it was brought to market? There is a tension here
between accuracy and stability. There is a need to review value based prices as evidence
accumulates or market conditions change. Whilst this would provide a more accurate cost of value it
would lead to price instability and confusion. Surveillance as results of trials are not always
replicated in the public at large and the appearance of delayed benefits or serious side effects could
trigger a review. Also, a change in market conditions e.g. entry of a generic into a therapeutic
market, could prompt a review.

**Setting the price:**
The value of medicines will cost the NHS and be taken out of the Health budget but could lead to
savings in other budgets, such as those in social care as people are able to return / continue to work.
Also, the ‘cost of attendance’ needs to be considered i.e. a person can now receive oral
chemotherapy in their own home rather than attending a hospital to receive this treatment.

The UK, whilst only representing around 3% of the global medicines market, sets the reference price
for 25% of the market. It is not clear if the price that is determined at a national level i.e. the VBP will
be used as the reference price, if so, this fact will need to be taken into consideration. However, if
there is a reference price and then a VBP the VBP may better reflect the true value of the medicine
to the UK market. The relationship between the VBP and the reference price needs to be developed
in partnership with the pharmaceutical industry and clarified for all. A possible scenario is that the
VBP is set at a national level but then discounted over a range in relation to volume of the medicine
purchased.

A decision also needs to be made and clarified as to whether or not the VBP system will allow for
negotiations at a local level, such as GP Commissioning Consortia (GPCC) in England, and we would
recommend that the system allows for local discretion and discounting. Companies will want to
make sure their prices are competitive in the market they are operating in and so the system should
be designed to take account of this. Also, there is a question if the VBP system will inhibit
commissioners and procurement officers in the UK from buying from other parts of Europe and the
consequences of this. Monitor, in its new economic regulator role, may have a role to play in a VBP
system and this should be further explored and clarified, particularly as most new medicines are
initially used within secondary care.

**Affordability:**
In the current NHS restructure the final decision on whether or not a medicine can be supplied will
be down to local determination e.g. GPCC in England. The affordability of a medicine and the local
variability that may result needs to be recognised and taken into account when a VBP system is
developed. It needs to be highlighted that not spending is not the desired goal, rather that spending
in ways which achieve desired outcomes efficiently is the end we are all seeking. Affordability, and
therefore subsequent patient access, will depend, in the main, on local flexibility within a VBP
system.
There is no mention of how a VBP scheme, which allows local flexibility, will work alongside Quality Standards and other elements in the system which could require local commissioners to fund clinical and cost effective medicines.

We are concerned that this consultation does not mention patient ‘top-up’ schemes as it is feasible that VBP could drive this locally. There needs to be further exploration of how patient-top up schemes may work alongside VBP.

**Specific Questions:**

1. **Are the objectives for the pricing of medicines as 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?**

   Conceptually it is difficult to argue against VBP as, in theory, it will create positive outcomes for patients and purchasers as well as an industry that thrives. However, there is still a great deal of uncertainty about what is meant by VBP, given that price and value are effectively synonymous. Perhaps a better and more accurate term would be ‘benefit-based pricing’.

   The objectives of VBP as set out in this document – in particular driving innovation to improve patient access and outcomes, are extremely far reaching and appear to go beyond that which can realistically be achieved through the pricing of branded medicines in the UK. We do not believe, as stated in the consultation document, that a VBP system in the UK will determine the direction of innovation with the global pharmaceutical industry unless it is part of a wider range of value based schemes implemented by other countries.

   We are not convinced that the VBP system will necessarily lead to improved choice or access to medicines for patients given that the new system would have to be introduced as a cost neutral intervention. A VBP system may generate changes to the measures of benefits and may make the system more transparent for patients to understand but we do not believe that it will lead to better access. In fact, we are concerned that it may lead to more postcode lottery of availability due to affordability issues at a local level.

   There are a number of conflicting objectives between rewarding innovation in the pharmaceutical industry, securing better value for the NHS and improving patient access and outcomes and these need to be explored more fully as a VBP system is developed.

2. **Should VBP 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?**

   Small patient numbers and the nature of some rare conditions can generate high treatment costs. The ethical decision-making framework developed to guide the deliberations of the Advisory Group for National Specialised Services (AGNSS) could provide a useful starting point for VBP, especially with regard to orphan medicines.² Those medicines that constitute the highest spend by the NHS should be prioritised for inclusion into the VBP arrangements as soon as possible.

3. **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 VBP?**

   We have no comments on this question.

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² The Challenge of rarity –Putting the N in the NHS: England’s new approach to commissioning services, products and technologies for small patient populations> Specialised Healthcare Alliance
4. 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? It would be extremely difficult to determine which disease is less severe, as for the patient that has that disease it is extremely severe.

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

6. 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? We would not support a system that has more than one price for a medicine as this would represent significant challenges in practice. There would need to be improved IT systems in place that were interoperable and transferred the required information to all the supplier systems involved. The system would also need to be able to track the individual patient. We would suggest that an average price was used, based on indication and volume, but recognise that such as structure would require further exploration.

7. 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 theory, innovations that address severe unmet need should attract a higher value, influenced by the number of patients needed to be treated. However, a wider range of considerations needs to be taken into account, for example:
   - Medicines taken in combination to improve efficacy e.g. velcade and dexamethasone
   - Medical devices that improve the delivery of medicines
   - Companion diagnostics that can provide information on the probability that an individual will have a positive response or develop a specific adverse reaction

   The use of Quality Adjusted Life Year (QALY) as a value is optimistic as it relies on all the systems working and everything being in place. It does not take into account additional service costs such as associated attendance costs for administration in secondary care.

   We do not believe that the development of a UK VBP system alone will influence the global pharmaceutical industry in relation to the development of medicines that the UK may find innovative. However, premium payments for innovations require further exploration.

8. In what ways can we distinguish between levels of innovation? See our response to question 7 above

9. 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? and

10. 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.

   We believe that an open and transparent system of decision making is required when value and prices are being determined. This system needs to go beyond clinical and cost effectiveness and take into account the benefits seen across society in a structured and consistent manner.

   The issue of weighting is extremely complicated. The NHS constitution states that ‘everyone counts’\(^3\) so it would be difficult to give certain members of society more weighting than others. It

\(^3\) Department of Health 2010: The NHS Constitution; the NHS belongs to us all

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is difficult to visualise a framework which would allow the consideration of wider societal benefits and how weightings could be assigned and how this would relate to value for these benefits. If VBP is to truly capture wider societal benefits then it has to be an initiative that is developed and adopted across all governmental departments and policy.

Expert opinion is frequently exercised in the individual patient’s best interest rather than in the best interest of the population as a whole. So, although we all recognise that there needs to be a system of rationalisation within healthcare, the reality is that individuals will seek access to best treatment for themselves and their family members. Therefore, we do not believe that VBP alone will eliminate the system of winners and losers. We do not believe that VBP will empower clinicians at the individual patient level or that patient’s access to treatment will be radically improved. However, the development of a VBP system could potentially lead to a more open and honest discussion around rationalisation.

We would suggest that specialist clinical networks, such as the cancer networks, are involved in the development and implementation of any weightings. These networks should continue under the new NHS structures in England so GP Commissioning Consortia and NHS Foundation Trusts can refer to them for advice.

11. **How can we best derive the different categories for burden of illness and therapeutic innovation and improvement?**
These would need to be developed using a wide a range as expertise as possible including professional bodies, health economists and patients. The pharmaceutical industry must also be involved in the development of categories and the evaluation system.

12. **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?**
Risk sharing schemes, resulting from negotiation between the payer and the pharmaceutical industry on who bears the risk of non-achievement of the intended goal, could be an option if there is insufficient evidence. We are aware that such a system would require further exploration as we believe that such schemes are a major drain on resources. The consultation mentions removal of patient access schemes so this may not be a viable option.

13. **Does the system set out above describe the best combination of rapid access to prices and affordability?**
We do not believe that there is sufficient detail in the consultation document to enable us to comment on this question.

14. **In what circumstances should a value-based pricing assessment be subject to review?**
A balance needs to be struck between bureaucratic burden and the need to review the VBP as a result of, for example, patent expiry, the entry of a cheaper generic and significant new evidence becoming available. However, consideration also needs to be given to the fact that it is unlikely that the industry would submit evidence which would lead to a lower VBP for their product.

In the pharmaceutical industry, several companies may be working on the development of products for the same disease areas. If one company releases their product to market first, how will VBP place a value and a price on similar products launched after the originator?

15. **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 Cancer Drugs Fund obviously only applies in England.
In many ways the administering of the cancer fund has been pre-empting the arguments for a VBP system. The system seems to be working in the following way:

- A list of medicines has been drawn up and is being evaluated centrally for cost effectiveness
- These medicines are being priced by the pharmaceutical industry with a list price (for reference pricing) and a series of regional or national arrangements that deliver a VBP on the basis of an online discount, a volume framework and/or retrospective discounts

Although any transition will need to be carefully controlled the closeness of the model would facilitate a change to VBP, as long as the final model is not too dissimilar.

16. **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?**

From the detail contained within this consultation document it is difficult to clearly state whether or not the proposed outcomes will be achieved via a VBP system and we believe that a lot more work and discussion needs to be had before such decisions can be made. There are a number of important areas that require further consideration:

**Greater innovation:**
We believe that the consultation document presents a simplistic view of how innovation is directed and driven within the pharmaceutical industry. It does not recognise the incremental nature of scientific discovery or how to place a value on advances in science that are part of a continuum of steps to better health care, as opposed to a product by product approach. Industry does currently plot unmet medical needs and assess this against the ability to deliver. VBP may make a small contribution to global direction but it will not direct innovation. The increasing production of generics in other countries, such as China and India, is currently having a negative impact on the innovation cycle funding. We believe the question is more around how, when there is innovation, this is handled in a public health context. Innovation is global and will not be directly influenced by the UK pricing system.

The current debate on VBP has excluded any assessment of the desirability of varying periods of intellectual property protection (either longer or shorter) for pharmaceuticals. This is a critical determinant of the overall cost and value of a medicine and, we believe, should be included as part of the debate on VBP.

**Broader and transparent assessment:**
There is a need to understand how the pricing decisions will be made and by whom. The decision making process and resultant outcomes need to be open and transparent and also robust enough to undergo challenge through judicial review. There is some concern that the proposed VBP system will be less transparent than that currently delivered via NICE and SMC. It appears that the effectiveness review via NICE and SMC will continue to be publically available, but there is much uncertainty as to whether the pricing/value decision making process and outcomes will be made publically available. There also needs to be clarity about who will make these pricing/value decisions and how a manufacturer or patient population might seek redress.

**Better value for money for the NHS:**
A balance needs to be struck between national decision making to reduce variability at a local level and sufficient flexibility at a local level to allow for discretion and discounting. The consultation document does not make it clear to what extent individual GP CC and the NHS will be able to negotiate independently with the pharmaceutical industry for discounts once a VBP
has been agreed at a national level. It is also unclear as to how cheaper, parallel imports will fit into a VBP system and this needs to be explored further.

17. Are there other factors not mentioned in this document which the new system should take into account?
   This question is answered in our whole response as we believe there are many factors that the new system needs to take into account which have not been mentioned in the consultation document.

18. 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?
   **VBP and Reference price:**
   There is uncertainty as to whether the VBP will also be the reference list price for a medicine and what impact this is likely to have on the UK pharmaceutical industry. If the VBP is not the reference price, it is likely to then be a ‘hidden’ price – this would not sit well with the drive for a fairer and more transparent pricing system and we believe that commercial confidence should not be used as a blanket to transparency. A system that enables a value based rebate with volume agreements, could, in part, address this issue and this has recently been explored in a paper by Claxton et al.⁴

   If a value is set at a national level but not accepted locally, or the medicine is not used locally due to affordability issues this could be a big risk to the system. If VBP is to be successful one part of the system cannot disregard another.

   **Patient choice and postcode lottery:**
   There is concern about how a VBP system will interplay with the patient choice agenda. The system will allow for choice about treatments and treatment options, and also information about treatments, but it is not clear how this integrates with affordability issues. Choice has traditionally been about the provider and patients may wish to choose their GP practice based on the availability of treatments. Greater candour is required to articulate that, whatever the VBP, local affordability will determine access and there needs to be a balance between local decision-making with equitable, high quality care for all.

   **Devolved NHS:**
   Greater clarification is sought on how the VBP system will operate across the devolved countries. There is concern that there may be differentials in weighting in the different countries. Basically this appears to be a UK VBP system but needs to be applied and implemented across different management systems at the devolution levels.

19. What steps could be taken to ensure that value-based pricing has a positive impact in terms of promoting equalities?
   There is a danger of introducing more inequalities into the market unless the issues of affordability are more strongly linked to value. It is essential that any system that is introduced is as simple and easy to understand as possible.

20. Are there any other comments or information you wish to share?
   Clearly the development and implementation of VBP will be an iterative process in the lead up to 2014. Further consultation and engagement with pharmacy will offer expertise in areas such as

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manufacture and industry, technology appraisal, medicines procurement, prescribing and dispensing.

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