

**A new value-based
approach to the pricing
of branded medicines: a
consultation**

Reply Form

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Response form

Name: Ben Cottam
Contact address: 1 St Andrews
Place, Regent's Park, London

Organisation representing (if
appropriate): The Faculty of
Pharmaceutical Medicine

Postcode: NW1 4LB
Contact telephone: 020 7224 0343
Email: b.cottam@fpm.org.uk

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

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?**

Yes No

Comments

The Faculty of Pharmaceutical Medicine (FPM) is a professional membership organisation with approximately 1,400 members who are practising or retired pharmaceutical physicians or those with a professional interest in the speciality. The FPM's mission is to advance the science and practice of pharmaceutical medicine by working to develop and maintain competence, ethics and integrity and the highest professional standards in the specialty for the benefit of the public. The Faculty seeks, through its activities, to bring about an improvement in the health of the public.

The FPM welcomes the opportunity to respond to this consultation on value-based pricing (VBP). Whilst we broadly agree with the concept of value-based pricing we have some concerns about its implementation and the impact on our members, the pharmaceutical industry and the health of the public, which are outlined in our answers to the consultation questions. We are committed to ensuring that the best value medicines are available to patients, and would be keen to remain as stakeholders in the onward development of the new system.

The Secretary of State's Foreword and the Introduction to the consultation contain some fundamental misunderstandings. They suggest that companies need a more stable and transparent pricing system with clear signals about priorities. Currently the diseases with the most industry sponsored research activity are cancer, heart disease and stroke, Alzheimer's disease and rheumatoid arthritis which certainly correlate with the Government's priorities. These passages in the document also appear to fail to recognise that most innovation is incremental and not genuine breakthrough.

With regard to para 2.17 it should be recognised that line extensions come in many forms, from a new formulation to a new indication, and these can often be beneficial to patients. For example a new formulation may mean that patients only need to take a medicine once a day thus improving adherence.

The FPM agrees that the objectives for pricing of medicines are adequate. However, we have concerns that the pharmaceutical industry will have sufficient short to medium term return to sustain the investment required to be able to deliver this over the next few years. If this return is inadequate, it is likely to further drive R&D investment away from the UK.

- **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?**

Yes

No

Comments

The FPM does not believe that VBP should apply to existing medicines as the current Pharmaceutical Price Regulation Scheme (PPRS) allows for a regulation of access/profit based upon that price. However, we believe that it may be appropriate for some specific medicines (perhaps above a certain acquisition price or total annual cost) to be re-evaluated under the new scheme if there is a substantial patent remaining. However these should not be subject to a full review, but a simpler check to ensure that there is not a complete mismatch between the VBP and the PPRS price within certain percentage banding.

- **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?**

Yes ✓

No

Comments

Orphan or ultra orphan drugs should be managed separately as these indications will be rare by definition (prevalence less than 1:2000 population) and there will be no incentive for development unless a different situation is in place to provide specific incentives or reflection of the needs and risks (with low return) in these areas.

With regards to price thresholds, the FPM believes that the benefits of a medicine should be determined from data with the new product or modelled as appropriate and then the lifetime value or cost avoidances of those benefits applied to determine the value of the medicine. The ability to reflect the possible future value of a medicine or the line extension value that is demonstrated by outcome data at a later date is important to consider.

We would like clarification as to whether the price of a medicine will rise when more value is demonstrated by outcome data? Would there be the possibility of early use and adoption while more data is being collected? If so, what would be the situation to resolve the price at market entry? Would a low price be charged that would rise, or would a high price be charged that could be rebated if it failed to demonstrate the benefit?

- **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?**

Yes ✓

No ✓

Comments

The FPM agrees that paying more for a greater need makes sense, although we wish to point out that many medicines and treatments which are initially thought of as somewhat niche go on to prove widely effective, such as ACE-inhibitors for hypertension, which very possibly might not have been recognised or priced appropriately at launch under these proposals.

More information is needed on how thresholds would be set and how they would work. Would there be thresholds per indication or per disease area or long vs. short term impacts (i.e. primary/secondary prevention vs. treatment).

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

Comments

It will require different presentations or licences for the same New Chemical Entity (NCE) for different indications, or the recording of the diagnosis on the prescription to achieve the most appropriate VBP for each indication. This would be very difficult to enforce and therefore we do not believe this would be appropriate at least until the VBP system has evolved i.e. at least five years after initiation. This also fails to take into consideration off-label prescribing.

- **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?**

Comments

It will need to be carefully managed to ensure that budget holders do not automatically denote the cheapest indication to save money. Electronic prescribing will help this if it can be linked to the diagnostic codes used for epidemiology purposes as these are more likely to be accurately recorded.

- **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?**

Yes

No

Comments

The FPM believes that there is a need to recognise that most innovation is incremental and not genuine breakthrough. Para 4.22 recognises that reduction in side effects may be beneficial and this was demonstrated in the ACE inhibitor class, where the first in class, captopril, had coughing as a significant and common side-effect. Later medicines in the class have tended to have coughing as a far less prevalent side-effect and therefore be more acceptable to patients. It may become evident during the development of a drug the size of the effect likely to be seen, but even at the time of approval and launch it is not always clear whether a product is a breakthrough. However, we recommend that innovation should command a higher price particularly

if it explicitly demonstrates a high outcome value. If the benefit can be modelled or hypothesised by the novelty of the mode of action, this should also command a higher price, contingent on the demonstration of the outcome. However, it should be noted that compliance benefits from reformulations or better tolerability can also improve cost-effectiveness and improve treatments.

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

Comments

The FPM believes that ultimately the levels of innovation are determined not by mechanisms (unless they deliver clinical benefit) but by the demonstration of that benefit. Furthermore, the level of innovation may not be clear at launch e.g. the continuing new indications for aspirin over its life-cycle.

- **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?**

Comments

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.**

Comments

The FPM recommends that an additional measure be used, that is more sensitive than a QALY, and that reflects the impact of the treatment on carers etc., then this is to be welcomed. We recommend that disease specific tools should be developed as necessary i.e. a measure that reflects the impact on carers. The implication is that the QALY (and its threshold) will remain the standard for use. The QALY is somewhat insensitive and does not measure changes in health status effectively particularly in end of life care where prolongation of life is not well represented.

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

Comments

No comment

- **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?**

Comments

The FPM recommends that the role of NICE should be supported, but only if they can be included in pre-launch advice and that the advice and cost/value discussions are generally binding and therefore immediately implementable. If a company delivers what has been requested then the price should be justified and not challenged.

The question relating to long term data implies a cost rise rather than a high price from the start. This may be acceptable, but if a company manages to deliver the outcome data required for the higher price 4 years after launch will the NHS pay the marginal cost for the value they have accrued over this time? To gain use and acceptance, companies may accept the lower price initially, but as above there must be a commitment that if data are generated the VBP will rise and be funded as agreed without delay.

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

Yes ✓ No

Comments

Ensuring rapid adoption of these new medicines will ensure that the value determined to exist will not be denied to the public. Commissioners and consortiums should be measured and targeted to ensure the speed of adoption is appropriately rapid.

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

Comments

We believe that review should occur on approval of a new indication or outcome data. This process should not be hampered by undue delays, as the parameters for success will be able to be agreed in advance and if delivered, the price is justified.

- **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?**

Comments

During the agreement of funding via the Cancer Drugs Fund, an interim review should be put in place after a certain time period or number of patients have been exposed. Observational registries should be maintained and the value of the medicine determined from the data generated or in other studies that have reported during this time. Therefore, the CDF should not be shut down immediately and VBP should be implemented to allow those newly approved products to have the correct evaluation of time/exposure to fulfil their review period.

- **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?**

Yes ✓ No ✓

Comments

The FPM believes that this system can work. However, we caution that if only downstream value is considered and upstream investment and the level of pipeline attrition ignored it will fail in its ambitions of conserving a sustainable industry.

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

Comments

The FPM notes that the consultation makes reference only to branded medicines and not to generics and there seems to be an assumption that generics (whether branded generics or not) will not be subject to this system. While it is usually the case that a generic medicine is priced below the price of an originator brand, it is not necessarily so (if other discounting arrangements are made, the list price may be the same) and neither is it necessarily the case that a generic medicine will be priced below any threshold of predetermined value for the indication in use. We recommend that consideration be given to the future pricing of generic medicines in a value based pricing system.

- **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?**

Comments

The FPM believes that there is a risk that the NHS will only pay for what it thinks it needs and ignores the investment required to deliver that value. This is not to say that low value products should be paid at a premium price, but is to ensure that for VBP to be a long term success other things must occur. Partnership with academia, conditional approval and availability, early adoption of new medicines in concert with observational trials to demonstrate their worth and the facilitation of clinical trials must all make the UK an attractive place to research and develop medicines and will contribute to reducing these risks.

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

Comments

No comment

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

We would also like it to be noted that, whilst it is worthy that the price of any medicine should reflect the value that the product brings, it also must recognise that there is a wider economic value of research (i.e. employment), and the investment required to deliver that medicine. It is important that incentives (or recognition of the research and development effort) are built in here or elsewhere in parallel legislation or agreements to facilitate R&D staying in the UK.

We also believe that the proposals for changes to the regulation and governance of medical research in the recent Academy of Medical Sciences review provide an additional benefit and infrastructure for the conduct of studies to accelerate development and this could work to offset delays that impact on net present values.

We are concerned that companies may have to justify the reasons for an inability to provide a product at a price that 'relates to its value' when that price or the decisions taken by DH to determine that value based price may be erroneous or unrealistic and may also not reflect the full worth of the product (potential or real) and may also impact significantly upon the price differential in other EU markets and thus the ability of a manufacturer to recoup any investment from its product.

It must not be forgotten that the PPRS has served the UK well in providing price stability and therefore continuing investment by global companies in the UK. The introduction of VBP must maintain this situation and not become a mechanism for encouraging disinvestment. The UK is now the only country in Europe where a medicine can be prescribed on the day of launch, the VBP system must enable this to continue for the benefit of patients.

Many thanks again for receiving the recommendations contained in this document, may we reiterate our readiness to remain as stakeholders in the onward development of the new VBP system.

Before submitting your response to the Department, please make sure that it has been saved in a name that will make it easier for us to track. Many thanks.