STAKEHOLDER PERSPECTIVES ON VALUE-BASED PRICING

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After more than fifty years of regulating the cost of medicines through the Pharmaceutical Price Regulation Scheme (PPRS), the Government has embarked on an ambitious plan to move towards a system of value-based pricing (VBP) for new branded medicines from 2014 onwards.

Whilst the Government's intentions behind introducing VBP have been broadly welcomed, stakeholder opinion has divided substantially over the complexities of how to design and implement such a system – accentuated by the lack of detail in the Government's response to the initial consultation on VBP.

One of the biggest frustrations in this process is that there has been no forum available for stakeholders to come together to exchange their views on VBP. Stakeholders have been thinking in isolation and 'lobbying' Government independently rather than working together to ensure 'win-win' solutions to some of the underlying issues and disagreements.

To address this, and because VBP offers such an important opportunity, Myeloma UK decided to host a roundtable discussion to create such a forum.

Attendees at the discussion, including patient groups, health economists and industry representatives, examined the issues and 'critical success factors' fundamental to a new system of drug pricing, the 'fault-lines' in the VBP debate, and possible areas of consensus. Attendees also contributed to clear recommendations, summarised below, that we hope will move the VBP debate forward.

PRICE SETTING

In establishing a system of VBP one of the most critical issues that needs to be addressed is how prices are set.

Attendees agreed that value-based prices for new branded medicines should be arrived at through a clear and fully transparent process, able to withstand judicial review. However, in order to protect against the negative effects of international reference pricing, the actual reimbursement price reached through this process should remain undisclosed when necessary.

It was also recognised that the new system should include a mechanism for the price of a medicine to be adjusted to take account of new indications, thus representing its overall value to the NHS. This should not mean, however, that different indications of the same medicine should be priced differently, as this is impractical.

The question of the relationship between pricing and reimbursement arrangements and industry's location of research and clinical trials proved particularly controversial during the discussions.

Whilst some stakeholders perceived the two issues as unrelated, others feared that applying a downward pressure on prices would damage the existing 'ecosystem' and drive companies to relocate their clinical trials elsewhere.

In taking VBP forward, if stakeholders do consider this pivotal to the debate they should be explicit about why.

VOLUME AND UPTAKE

A primary objective of VBP is to ensure better access to effective drugs and innovative medicines on the NHS.

Whilst this is a laudable objective, attendees struggled to see a strong link between VBP as presently proposed and improved patient access to medicines. The issues surrounding patient access are complex, and drug-pricing only forms part of this bigger picture.

It was concluded therefore that additional policy initiatives would be required as part of VBP to ensure that approved new medicines are prescribed and available throughout the UK.

Furthermore, in order to understand the current problems with access and uptake, attendees called for improvements in data collection techniques across the NHS.

THRESHOLD SETTING

In light of the long-standing criticism of the National Institute for Health and Clinical Excellence (NICE) cost-effectiveness threshold (the cost/QALY threshold), attendees were asked to consider how thresholds should be set under VBP. This is particularly important as the Government has outlined its intention to create maximum prices for medicines based on a range of thresholds – depending on factors such as innovation, societal costs and benefits, disease severity, and unmet need.

Attendees agreed that thresholds should, for the first time, be based and set by a new, independent advisory body that would sit outside of the existing HTA organisations in the UK.

Attendees also recognised the value of wider Government engagement with patient groups and the public on threshold setting, since the potential application of varying thresholds has already proved one of the most controversial elements of the Government's proposals.

DEALING WITH UNCERTAINTY

The design of the new pricing system will have to address the challenges in certain cases of dealing with uncertainty regarding the clinical and cost effectiveness of new medicines at their launch.

Attendees agreed that through the use of different cost-effectiveness thresholds the Government should be able to accept a lower price in certain circumstances for medicines when there is uncertainty around the data.

To reduce uncertainty the Government needs to agree with industry the level of evidence that needs to be collected prior to launch to ensure that companies reach higher price thresholds with their medicines.

To address further the issue of uncertainty, after a medicine has been approved by NICE, it was agreed that the Government needs to ensure that NICE works with Commissioners to specify clearly how the new medicine will fit into clinically relevant commissioning pathways on the NHS.

NEXT STEPS

Myeloma UK believes that the best way towards resolving some of the outstanding issues and differences of opinion relating to VBP is through multi-stakeholder dialogue. It is our hope that discussions such as those we have outlined will provide a valuable contribution to inform the development of the Government's policy. We are keen to continue to provide stakeholders a forum to discuss these issues and look forward to holding further meetings to address the policy detail in the lead-up to 2014.

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