

## **Value-based pricing**

# UK debates new pricing model for pharma

Pharmaceutical companies in the UK are eagerly awaiting more information about the soon-to-be overhauled pricing regime for branded prescription medicines, the details of which are now being worked out by the government and the Association of the British Pharmaceutical Industry (ABPI) behind closed doors.<sup>1</sup> The aim of the new value-based pricing (VBP) system, due to take effect on 1 January 2014 when the existing Pharmaceutical Price Regulation Scheme (PPRS) expires, is “to recognise and reward innovation...and give patients access to the most effective medicines,” according to the Department of Health.<sup>2</sup>

In theory, the VBP regime is a win-win strategy for everyone from industry to the National Health Service (NHS) to patients. Industry should benefit from more transparency and should be able to anticipate how prospective products may fare. The NHS should operate on better value for money. And patients should get improved access to effective and innovative medicines.

In introducing VBP, the government envisions a more stable and predictable framework, where there would no longer be negotiations once every five years as under the PPRS. The PPRS sought to achieve a balance between reasonable prices for the NHS and a fair return for industry to plough back into R&D, but the government believes VBP could do better.

However, as the deadline for the new regime nears, very little is known about how the system will work in practice and, for companies, to what extent it will affect return on investment. Both the Department of Health and the ABPI have told *MedNous* that they are bound by a confidentiality agreement that prohibits them from discussing the new VBP system while they are in the midst of talks.

### **Central role for NICE**

Nonetheless, some information has been released, perhaps to appease mounting criticism. Most notably, this has come from the House of Commons Health Select Committee. The committee issued a report in January 2013 stating that it was unacceptable that the arrangements for VBP had still not been settled, given that the original consultation document on the matter was issued in December 2010.<sup>3</sup> It referred to VBP as a “nebulous concept” and called on the government to “bring this uncertainty to an end no later than the end of March 2013”.

The government issued a response on 21 March 2013, which offered assurances that progress had been made and revealed that the National Institute for Health and Care Excellence (NICE) would be responsible for the full value assessment of medicines under the future VBP system.

“Work to develop the new system builds on NICE’s existing technology appraisals processes, but it is also capable of incorporating a broader assessment of a medicine’s benefits and costs, taking into account factors such as burden of illness and wider societal benefits. Importantly, it imposes no requirements on companies to collect additional data,” the government said.

It confirmed that development of the overall VBP framework, including any key “weightings” used to reflect broader components of a new medicine’s value, would fall within the remit of the government. For example, medicines that treat a particularly severe condition or reduce a patient’s care needs might have weightings applied to them that result in a higher value determination than other medicines.

Other aspects of the new system, such as how cases will be managed in the event that NICE’s value assessment does not support a company’s proposed list price, will be left to the Department of Health and the branded pharmaceutical industry to work out.

The government added that the VBP would focus primarily on new medicines but “it is possible that a small number of existing drugs could be assessed under VBP”.

A committee spokesperson declined to comment when *MedNous* asked whether the committee was satisfied with the government’s response. As for NICE, its chief executive Sir Andrew Dillon said he looked forward to working with the Department of Health and stakeholders in developing the methods and processes for the new system. However a

spokesperson would not confirm whether NICE was already sitting at the negotiating table.

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### **The VBP scheme as proposed**

The government’s intention is that the VBP scheme will generally apply to new active substances placed on the market from 1 January 2014. It is expected to run in parallel with a new PPRS successor scheme, which will apply, for the most part, to medicines already on the market.

Simply put, the difference between a VBP system and the PPRS is that:

- VBP links the price of a medicine to the “societal value” it provides, taking into account the wider economic benefits of treatments beyond direct health gains (eg benefits related to reduced reliance on carers); whereas
- the voluntary PPRS gives pharmaceutical companies the freedom to price new active substances, but it controls these prices by capping the profits that companies are allowed to make from their sales to the NHS.

The VBP is meant to encourage innovation in areas of greatest unmet need. The idea is that, based on a VBP assessment, a range of maximum price thresholds will be put in place to reflect the different values that medicines offer. In theory, a single medicine with different indications could have multiple prices.

In its consultation, the government proposed a rough pricing structure as a starting point for talks with the ABPI. There would be a basic cost effectiveness threshold reflecting the maximum price the government would pay for medicines that offered no additional value. 'Additional value' would be measured in terms of innovation, targeting diseases with a high burden of illness (ie medicines focused on diseases with unmet need or which are particularly severe) or wider societal benefits. For medicines offering additional value, the maximum thresholds would be higher.

Under the existing PPRS, a standard cost-effectiveness threshold is applied to all new products. Although this sometimes takes into account additional factors such as societal preferences, the mechanism for doing so is viewed as ambiguous and lacking in transparency. One of the main aims of the government is to make the whole assessment process more transparent under VBP.

The manufacturer would be able to propose a list price for a new medicine under the new system. If this figure was equal to or less than the basic cost effectiveness threshold, that price would be accepted for the NHS. If the company's price was higher than that justified by the VBP assessment, it would be asked to lower the price or submit further evidence to justify its claim about the medicine's value.

## Medicines already on the market

Though the ABPI was unable to comment in detail, a spokesperson confirmed that the successor scheme to the PPRS for medicines that are already on the market – but not necessarily another PPRS – is being negotiated in parallel with the VBP regime. "The way the two will join up is being hammered out now in negotiations," he said.

Stakeholders have urged the government to ensure that the two run together seamlessly, especially as the vast majority of pharmaceutical company sales will be subject to the terms of the PPRS's successor for years to come. In the short-term, a maximum of 20-30 new medicines are likely to be assessed under VBP annually, according to the ABPI.<sup>4</sup>

The fate of certain medicines that are available via special programmes such as the Cancer Drugs Fund (CDF) and patient access schemes is also sketchy. The CDF was established to help provide cancer treatments that would not otherwise be available on the NHS. It was set up as an interim measure until the start of the VBP system.

The Health Select Committee says that before the fund ceases to exist, a mechanism needs to be developed to ensure that patients receiving CDF-funded medicines do not have their treatment discontinued. The government has assured the committee that arrangements will be put in place to make sure this does not happen, but the specifics remain unknown.

Patient access schemes, which pharmaceutical companies can propose under the current PPRS to facilitate access to some drugs that might not otherwise have been recommended by NICE, may fall by the wayside, too.

The rationale is that there will be no need for this type of arrangement because the objectives of VBP are the same, ie to facilitate patients' access to cost-effective, innovative medicines. This has led to concern that patients may no longer be able to get the drugs covered by these schemes.

It remains to be seen whether the government will set out criteria to determine which, if any, of the already marketed medicines might be subject to the VBP scheme.

## Other concerns

Aside from the lack of information about how the VBP regime will operate, stakeholders have expressed other concerns such as how the government will make sure the new system is consistently applied not just in England's NHS, but across the whole of the UK, including in the devolved health administrations of Scotland, Wales and Northern Ireland.

The ABPI has also emphasised that for the VBP regime to be successful, medicines must not be subjected to further local assessments once a value-based price has been agreed as this could cause barriers to access or uptake of new medicines.

In addition, stakeholders have questioned whether the VBP may influence companies' global strategies. A number of responses to the government's consultation suggested that companies may choose not to use the UK as an early launch market for their products, or may choose not to launch particular products at all, if they do not feel they are getting an adequate price. This phenomenon has already been seen in Germany since its healthcare reform law (AMNOG) took effect in 2011.

The biggest issue, however, is that of timing. The government has acknowledged that the new pricing arrangements should be finalised as soon as possible but has given no further information about timelines. Its intention was to carry out "an extensive programme of testing" of the new VBP model prior to its launch, but many have questioned how this will be possible with less than a year to go before the system needs to be in place.<sup>5</sup>

## References

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