Joint DH/ABPI statement on arrangements for pricing branded medicines from 2014

The Department of Health and the Association of the British Pharmaceutical Industry (ABPI) are committed to reaching agreement on a pricing system that gives patients better access to the most effective medicines, at prices that encourage the NHS to use those medicines when clinicians think their patients can benefit and deliver value to the NHS, and provide a fair reward for these innovative medicines.

When the current Pharmaceutical Price Regulation Scheme (the 2009 PPRS)[1] comes to an end in December 2013, we will move to new arrangements which will incorporate a broader assessment of value of a medicine, known as value based pricing, for new medicines (new active substances), in conjunction with a successor scheme to the 2009 PPRS.

The current branded medicines pricing scheme, the PPRS, is a voluntary scheme agreed between the Department of Health and the ABPI as the recognised body representing the branded pharmaceutical industry.

Our joint aim is to achieve a negotiated agreement for the new arrangements, including value based pricing. We expect negotiations will begin later this year and these will cover both value based pricing and the successor scheme to the 2009 PPRS. In addition to the voluntary arrangements that we hope to agree through negotiation, there will continue to be a statutory scheme[2] for those companies that choose not to participate in the voluntary arrangements.

The Government and ABPI are committed to strengthening the UK environment for life sciences. Government has set out a broad range of policy initiatives, including the Life Sciences Strategy, to support a sustainable industry based on innovation and the Innovation, Health and Wealth report addresses the importance of early adoption and diffusion of clinically and cost effective innovative medicines in the NHS. This

[1] The 2009 Pharmaceutical Price Regulation Scheme
[2] The current statutory scheme is defined in the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations, as amended

statement on the forthcoming pricing arrangements should be seen in the context of wider life science policy and its shared objectives.

Ahead of the negotiations between the Department of Health and the ABPI, we can identify a number of points and principles which will need to be taken into account in the new arrangements. This paper sets these out.

Underlying aims for the successor scheme to the 2009 PPRS

Successive PPRS agreements, which have evolved through negotiation since 1957, have delivered a stable and predictable pricing environment for the industry and NHS, which in turn has helped sustain the supply of innovative branded medicines to patients.

The successor scheme will cover the vast majority of branded prescription medicines already on the market before 2014. The scope is expected to be, broadly, medicines already licensed in the UK or the EU on 31st December 2013. The Government and ABPI's intention is for this scheme to operate under a similar but not identical framework to earlier PPRS agreements. It is important to note that over its long history, the PPRS has evolved to address changing needs. The scheme will operate under a similar but evolved framework to the 2009 PPRS.

We also want to improve the workings of the scheme to minimise bureaucracy, especially for SMEs, while considering what is needed to support smaller innovative companies.

As in all previous negotiations it will be important that the scheme is affordable and sustainable and responsive to evolving science and the changing needs of the NHS.

The Government and the ABPI believe it is important for the scheme to ensure stability and predictability in the framework for pricing of existing branded medicines to enable the NHS and industry to develop and manage their financial and investment plans. Therefore, as a first step towards achieving this, the Government and the ABPI have agreed that we are aiming for an agreement that will operate for five years from

January 2014. Every negotiation produces an evolved scheme that enables industry and NHS to respond to new challenges: it will be no different this time.

Objectives for the proposals for value based pricing

The Government and the ABPI believe it is vitally important that there is a continuing supply of innovative treatments that benefit NHS patients. Continuous research and development and competitive efficiency should be the keys to any company's success in a research-based industry. The ABPI welcomes the Government's perspective that value based pricing alongside a renewed PPRS should support this goal.

The Government's objectives for value based pricing are to:

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

The new agreement must therefore be stable and sustainable over the longer term, so that industry is able to plan and prioritise research in areas which can deliver the greatest potential benefits to patients and society.

There is a considerable degree of commonality between these objectives, and the objectives set out in previous agreements. In the 2009 PPRS these are:

- *deliver value for money;*
- *encourage innovation;*
- *promote access and uptake for new medicines;*
- *provide stability, sustainability and predictability.*

Value based pricing will be introduced in a planned and progressive way. It will focus primarily on new medicines (new active substances) placed on the market from 1 January 2014. There is the possibility that a small number of existing medicines might

also be assessed and – potential candidates might include some of those which are currently being funded through the Cancer Drugs Fund.

It will, of course, be essential to ensure that the new arrangements from 2014 form a coherent and complementary framework. Some elements may be common to both VBP and the successor scheme to the 2009 PPRS, whilst others will clearly need to be distinct. It would be premature, at this stage, to determine whether this is best presented in a single document covering both VBP and PPRS – what matters now is getting the content right.

A common medicines pricing policy across the UK

It is important that there is a common branded medicines pricing policy across the UK and we expect the new arrangements to form part of a UK-wide scheme. However, the Devolved Administrations determine many aspects of health policies, including those affecting the use and availability of medicines within their health systems. It will therefore be important to ensure close working with the health departments of the Devolved Administrations and with their HTA bodies to ensure a coordinated and coherent approach.

Pricing in the market

Within previous PPRS agreements new products designated as new active substances by either the EMA or MHRA are priced at the discretion of the company on entering the market within the profit cap of the PPRS. Within VBP the proposal is that companies would be free to propose a price for a new medicine at launch.

The Government intention is that the value-based pricing assessment is carried out as fully as possible, as early as possible. The intention is that the new arrangements should be stable and not bureaucratic. The Government believes companies will therefore be able to predict well in advance how prospective products are likely to fare. The assumption is that prices at launch will be set at a level that is close to their expected assessed value. The management of any cases where the value assessment does not support the list price will be considered during the negotiations.

Safeguarding access to clinically appropriate and cost-effective medicines

Through a funding direction, NHS commissioners in England are currently normally required to fund medicines and treatments in line with NICE recommendations. It is important that there is rapid and consistent implementation of NICE Technology Appraisal Recommendations throughout the NHS in England.

The Health and Social Care Act 2012 includes provisions that allow for the effect of the funding direction to be replicated as the NHS moves to new structures. The Government's intention is to maintain the effect of the funding direction for medicines which have successfully come through a value-based pricing assessment. The NHS in England will continue to be required to fund medicines already recommended by NICE, as well as medicines subject to the value based pricing regime. This means patients will continue to have access to clinically appropriate, cost-effective medicines and treatments as set out in the NHS Constitution and accompanying handbook.