Patient Access Schemes and Flexible Pricing: statement of outcomes from the review of the pricing flexibility measures under Chapter 6 of the 2009 PPRS

Introduction

1. The Pharmaceutical Price Regulation Scheme 2009 (PPRS) set out two new pricing flexibility measures that were aimed at linking more closely the value of medicines to what the NHS paid for them through a pragmatic and systematised approach in the PPRS. The two mechanisms are Flexible Pricing and Patient Access Schemes. Details are set out in Chapter 6 of the PPRS.

2. In view of the novelty of these arrangements, the PPRS made provision for their early review in the light of experience. The Department of Health and the ABPI met in late 2010 to agree terms of reference for the review, and the review was carried out in the first half of 2011.

Key findings from the review

3. Patient Access Schemes (PAS) have proven a useful tool within the 2009 PPRS in facilitating patient access to some medicines that might not otherwise have been recommended by NICE. To date, including PAS agreed under arrangements in operation prior to the 2009 PPRS, [17] PAS have been incorporated by NICE as part of positive (or partially positive) appraisal guidance, helping to facilitate greater access for NHS patients to medicines for conditions such as arthritis, macular degeneration and a range of cancers.[1]

4. Although we do not yet have experience of applications under the flexible pricing mechanism, this option is seen by companies as potentially useful and remains open within the terms of the 2009 PPRS. The availability of the pricing flexibilities has had a positive impact on global pharmaceutical companies' perceptions of the UK as an environment that supports and encourages innovation.

5. As our experience in relation to PAS has increased, we have gained valuable knowledge and insights. This learning has over time enabled the development of proposals which are simpler and easier to implement, such as simple discount arrangements.

6. The process for considering proposals has also been improved with the creation of the Patient Access Scheme Liaison Unit (PASLU) at NICE and

[1] A list of operational PAS is available from the NICE website: (http://www.nice.org.uk/aboutnice/howwework/paslu/ListOfPatientAccessSchemesApprovedAsPartOfANICEAppraisal.jsp)

its Expert Panel, which includes representatives of the NHS, patients and the public and the pharmaceutical industry. The Department of Health and the ABPI would like to take the opportunity to recognise and thank Expert Panel members for their continued hard work and contribution. Recognising the experience that has been built up since the original PASLU process was published and the learning from this review, NICE will publish the updated PASLU process for consultation with stakeholders.

7. We recognise that there is scope for further improvement. For example, we have heard that companies would welcome more guidance on the process for making PAS proposals and the issues they should consider when doing so. Following this review, the Department of Health and the ABPI will, with input from NICE, collaborate to produce guidance to further consolidate the learning and experience gained to date to support companies in designing and putting forward proportionate patient access schemes which are fit-for-purpose for the particular issues they are intended to address.

8. In order to maintain confidence in PAS and ensure that their full value to patients and the NHS is realised, it is essential to ensure that their individual and cumulative impact on the NHS remains manageable. The recent trend towards simpler PAS is encouraging. The development of the accelerated process for simple discount PAS proposals has also played an important role. The selection of the preferred model for a specific PAS proposal remains a matter for companies, but where a more complex model is proposed, companies should be able to explain and justify their choice.

9. We have also learnt that there is sometimes some confusion about the distinction between Patient Access Schemes and other schemes offered direct to NHS bodies by pharmaceutical companies outside of or prior to NICE guidance being issued. We understand that it would be helpful to make sure stakeholders have easy access to information that clearly explains which arrangements constitute a PAS, in the context of a NICE appraisal, and which arrangements are locally based, and therefore discretionary.

Next steps

10. In light of the findings of the review, the Department of Health and the ABPI have agreed to take the following action:

    (i) **We will only describe schemes recommended as part of NICE appraisal guidance as “Patient Access Schemes”, and will request that companies do the same; we will also ensure that information about these operational Patient Access Schemes is easily accessible;**

    (ii) **We will work together to produce further guidance for companies on proposing Patient Access Schemes;**

(iii) **We will work together to produce a 'process map' and narrative illustrating roles and responsibilities in the PAS proposal and consideration processes;**

(iv) **NICE will publish the updated PASLU process for consultation with stakeholders, reflecting the learning from this review;**

(v) **We will explore opportunities to better understand the impact of Patient Access Schemes, including the extent to which projected benefits are realised in practice.**

(vi) **We will support companies in exploring the viability of specific flexible pricing proposals if these are put forward in the future.**

Background notes

11. The terms of reference agreed for the review of the pricing flexibilities within the 2009 PPRS were:
    A. *To explore experiences of patient access schemes and flexible pricing arrangements, including an assessment of what benefits they have delivered to date;*
    B. *To analyse potential barriers and challenges associated with the use of these mechanisms;*
    C. *To identify opportunities within the terms of the 2009 PPRS for improvements to the current arrangements for patient access schemes and flexible pricing, including arrangements to support the more systematic use of patient access schemes, by tackling identified barriers and challenges.*

12. The review was carried out within the context of the 2009 PPRS. Views expressed and conclusions reached by either party are without prejudice to broader discussions about medicines pricing or other related matters.

13. A Patient Access Scheme is a scheme proposed by a pharmaceutical company and agreed between the company and the Department of Health, with input from NICE, in order to facilitate patient access to cost-effective innovative medicines. Patient Access Scheme proposals are made in the context of a NICE technology appraisal with the purpose of improving the cost-effectiveness of a drug. A full list of operational Patient Access Schemes with links to the relevant NICE guidance is available from the NICE website at:

http://www.nice.org.uk/aboutnice/howwework/paslu/ListOfPatientAccessSchemesApprovedAsPartOfANICEAppraisal.jsp

14. Flexible pricing recognises that the initial launch indication of a medicine may not fully reflect its longer-term value to patients in the NHS. It allows companies to propose an initial price for a medicine that reflects value at launch, while retaining the freedom to increase or decrease this original list

price either as further evidence or as new indications for the medicine emerge and change the effective value that the medicines offers to NHS patients. To date, there have been no applications under the flexible pricing mechanism.

15. The PPRS notes that, while pricing is a reserved matter, certain aspects of the pricing flexibilities relate to devolved matters. In view of this, the review focussed on arrangements in place for England and Wales. Key stakeholders in the Devolved Nations, including in particular the Devolved Administrations, were kept informed during the review process, and the outcomes of the review have been shared with them.

16. The review has been conducted jointly by the Department of Health and the Association of the British Pharmaceutical Industry (ABPI), as the parties to the PPRS agreement. We are grateful for the input received from a range of stakeholders including: pharmaceutical companies, NHS organisations, professional representatives, the Office of Health Economics and the National Institute for Health and Clinical Excellence, and in particular, the Patient Access Schemes Liaison Unit (PASLU) at NICE.