

**PHARMACEUTICAL PRICE  
REGULATION SCHEME (PPRS)**

Final Government response  
to recommendations aimed  
at Government contained in  
the OFT report “The  
Pharmaceutical Price  
Regulation Scheme”

JUNE 2009

## Introduction

1. In February 2007 the Office of Fair Trading (OFT) published its market study into the Pharmaceutical Price Regulation Scheme (PPRS)<sup>1</sup>.

2. The OFT had launched the study into the PPRS in September 2005 to assess whether the scheme was providing an effective way of meeting its stated aims:

- to secure the provision of safe and effective medicines for the NHS at reasonable prices;
- to promote a strong and profitable pharmaceutical industry capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines;
- encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries.

3. In its report, the OFT recommended that the Government should reform the PPRS, replacing current profit and price controls with a value-based approach to pricing which would ensure the price of drugs reflected their clinical and therapeutic value to patients and the broader NHS.

4. The OFT report effectively challenged the Government to ensure that the PPRS delivered on a number of fronts including whether it delivered value for money, whether prices truly reflected the value of drugs, whether innovation was appropriately rewarded, and whether it provided the stability required by the pharmaceutical industry. The report therefore made an important contribution to the debate on how the PPRS, which has been in existence for over 50 years, should evolve to ensure it is fit for purpose in the twenty first century.

5. The Government published its interim response to the OFT's report in August 2007<sup>2</sup>, welcoming it as a helpful contribution to an important debate. In fashioning a way forward, the Government said in its interim response that it would take into account the following principles:

- **Delivering value for money:** We agree with the OFT that we need better mechanisms to deliver fair prices and value to the NHS, to patients and to the taxpayer. We also need to ensure that the drugs bill is affordable for the NHS and that investment in other cost-effective elements of patient care is not adversely affected.
- **Assist the uptake of new medicines:** We are also committed to increasing the uptake of new cost-effective medicines in the NHS. Important progress has been made in this area since the creation of the National Institute for Clinical Excellence (NICE), but we accept that there is scope for further improvement in the uptake of cost-effective new drugs.

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<sup>1</sup> [http://www.offt.gov.uk/shared\\_offt/reports/comp\\_policy/oft885.pdf](http://www.offt.gov.uk/shared_offt/reports/comp_policy/oft885.pdf)

<sup>2</sup> <http://www.berr.gov.uk/files/file40756.pdf>

- **Encouraging and rewarding innovation:** The role of the pharmaceutical industry in the development of healthcare and medical advances is of crucial importance. It is in all of our interests that any pricing system will encourage research and reward innovation which delivers valuable new treatments.
- **Provide stability, sustainability and predictability:** It is important that, once introduced, a future pricing scheme provides stability, sustainability and predictability for industry. The OFT identified this as an important area and industry has stated on a number of occasions that the stability of the UK market makes it an attractive place to invest. We want to ensure that the UK remains a stable market over the coming years.

6. The Government said it would discuss these principles with the industry and make further proposals as part of the renegotiation of the PPRS also announced in August 2007. This renegotiation was concluded in December 2008 with the publication of the 2009 PPRS.

7. Further, in December 2007, OFT published its market study into medicines distribution in the UK. The market study considered the impact of manufacturers introducing direct to pharmacy (DTP) schemes and/ or reducing the number of distributors they use. The OFT made recommendations around discounts obtained by pharmacies.

8. Government responded to the study on 2 May 2008, agreeing that the recommendations made by OFT should be discussed as part of the current PPRS negotiations. However, it was not convinced of the need to bring forward legislation to clarify service standards at this stage, but said it would keep the matter under review. The 2009 PPRS contains provisions for the cost of changes in distribution models to be considered under the scheme and hence contributes to the Department's actions in response to the OFT's medicines distribution report with regard to potential increase in costs.

9. This response looks at how the four principles set out in the Government's interim response to the OFT's PPRS market study report are reflected in the agreed 2009 PPRS between the Government and the industry. The OFT report on the PPRS played an important role in informing both the PPRS negotiations and the new 2009 agreement. The response also shows how developments have already started to address the issues raised by the OFT. It also shows how the new PPRS agreement has addressed the challenges set out in the OFT's report. Further, this response looks at how PPRS 2009 has addressed concerns about costs set out in the OFT's report on medicines distribution.

## **The 2009 PPRS**

### **Delivering value for money**

10. The OFT's report set a challenge for Government by suggesting that the Government could deliver better value for money by making further savings in the drugs bill and by ensuring that prices better reflect value.

## **Delivering savings**

11. The OFT report suggested that savings of around £500 million could be made if out of patent branded medicines were priced closer to their generic counterparts. The Government has already taken a number of steps to ensure that value for money is delivered and savings are made to the benefit of patients, the taxpayer and the NHS. To date the UK has been particularly effective at implementing demand-side measures, including the provision of comparative information on levels of prescribing, to encourage clinically appropriate generic prescribing and the appropriate use of off-patent drugs within a particular class. These measures have contributed to a generic prescription rate of 83% of all items, giving us among the highest rates of any health system. In addition, the National Audit Office<sup>3</sup> has recently updated calculations contained in its 2007 report *Prescribing costs in primary care* and has estimated that £400 million was saved in 2008 through more cost-effective prescribing practice. However, the Government recognises the importance of making further progress on savings from the appropriate use of lower-cost generic drugs.

12. The OFT had proposed introducing provisions linking the price of out of patent medicines to the price of generics in its report. These were considered as part of the PPRS negotiations, and the final PPRS included different provisions aimed at ensuring savings are targeted at out of patent medicines. Subject to discussions with affected parties, the Government will introduce generic substitution in 2010. It believes this measure will continue to promote a strong generics market in the UK and ensure that the NHS secures best value from the appropriate use of generic drugs, delivering further savings that can be invested in patient care.

13. The Department of Health also believes that it is vital to achieve value for money in the price the NHS pays for branded drugs. That is why the 2009 PPRS included a price reduction of 3.9% in the list price of branded medicines sold to the NHS from 1 February 2009 and a further reduction of 1.9% from 1 January 2010. There will be further price adjustments each year, as the proportion of savings from generic substitution varies with time. However, the price cuts negotiated are part of a balanced package that continues to encourage a strong pharmaceutical industry capable of investing in future research.

## **Better reflecting value**

14. The OFT's report also called on the Government to ensure that drug prices better reflect their therapeutic value. The Government believes that value is already reflected to a certain extent in the way that drugs are purchased by the NHS. Currently, the way the NHS operates gives manufacturers a clear incentive to set prices that reflect the therapeutic value of drugs. A drug is more likely to be purchased by trusts if there is sufficient evidence to suggest that its price is a reasonable reflection of its value. Thus, manufacturers are encouraged to set prices that reflect value to and support

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<sup>3</sup> See [www.nao.org.uk](http://www.nao.org.uk)

uptake by the NHS. NICE has made a significant contribution to this process through its health technology appraisal guidance, which indicates clearly to the NHS whether and under what circumstances the use of a particular drug is both clinically and cost-effective. The Government and NICE continue to work together to ensure that the NHS has authoritative advice on significant new drugs at the earliest opportunity.

15. However, the challenge set by the OFT led to an important debate reflected in the PPRS negotiations about how value could be better reflected in the PPRS. Both industry and Government recognised this was an important point that needed to be taken forward. There is still scope to improve the way in which prices reflect value. This is why the PPRS has sought to introduce new mechanisms to encourage companies to provide medicines at a price which better reflects their value through the following two options:

- new and more **flexible pricing arrangements** that will enable drug companies to supply drugs to the NHS at lower initial prices, with the option of higher prices if value is proven at a later date; and
- a more systematic approach to the use of **patient access schemes**, which allow drug companies to offer discounts or rebates which reduce the effective cost of a drug to the NHS.

#### *Flexible Pricing*

16. New flexible pricing arrangements will provide greater flexibility for prices to change with time and to reflect changes in value. These arrangements will enable drug companies to supply drugs to the NHS at lower initial prices, with the option of introducing higher prices if a greater value is proven after launch, meaning that prices will better reflect the value of the drug, an issue identified in the OFT report.

17. Flexible pricing arrangements will take two forms:

- i. where significant new evidence is presented that changes the value of the drug under an existing indication, or
- ii. where a new licensed indication for the drug is shown to hold greater value than the initial indication.

18. Under the second form of arrangement, a simple discount will be introduced to ensure that the drug's price does not change for the original indication. Flexible pricing will only apply when medicines are subject to NICE appraisal as a review by NICE will be required to determine whether the revised price provides value to the NHS. The price change will only apply if NICE issues a positive appraisal for the drug at its new price using its established methods for assessing clinical and cost-effectiveness.

#### *Patient Access Schemes*

19. In recent years, the Government and industry have developed Patient Access Schemes (PAS), which are arrangements reached between the

Department and a pharmaceutical company allowing manufacturers to offer discounts or rebates to reduce the effective cost of a drug to the NHS.

20. The 2009 PPRS introduces a more systematic approach to these PASs, outlining transparent principles under which they will be assessed by the Department before being put forward for NICE appraisal. Decisions on how such schemes impact on NICE's recommendations remain a matter for NICE, and the arrangements that have been agreed fully respect NICE's independence in formulating its appraisal guidance.

21. Government and industry have agreed that the cumulative burden on the NHS must be kept to a minimum to ensure that the administrative burden – whether for individual schemes or collectively – is reasonable. The new processes ensure effective consultation with the NHS takes place and it is expected that these schemes will be the exception and not the rule. As agreed in the 2009 PPRS, the full costs to the NHS of any such arrangements will also be included in the costs considered by the NICE Appraisal Committee.

#### *NICE's economic perspective*

22. The OFT report also stated that in the NICE appraisal process, the 'notion of therapeutic value should embrace not just benefits to the patients themselves but to others who are affected by their condition, such as carers', though it did not support this with any specific analysis of the rationale for or impact of such an approach. This point has been raised in other fora, including the Health Select Committee's 2007 report on NICE. Whilst the Government recognises the importance of looking at this issue in more detail, any change to NICE's economic perspective would take place in the context of a fixed overall NHS budget. There would therefore be winners and losers from any changes to the weights NICE attaches to different benefits. For example, if NICE were asked explicitly to take account of impacts on economic productivity that could increase the priority attached to interventions to tackle chronic conditions such as back pain, this would in turn decrease the priority attached to treatments for other diseases such as those that largely affect older people, or people with end-stage terminal illnesses.

23. The Government does however believe that there is further merit in examining the consequences of potential changes in this area. The Department organised a series of working groups with stakeholders to discuss the issue further. Following on from these discussions, and in line with their conclusions on the need for further exploratory work, the Government has commissioned an independent study by the University of York into the potential effects of extending NICE's economic perspective. This study will report later in 2009.

## **Assist the uptake of new medicines, encouraging and rewarding innovation**

24. The OFT's report highlighted the need to focus on efforts to increase the uptake of cost-effective innovative medicines by the NHS, which has also

been raised by a number of stakeholders. The Government recognises that it is vital to address this point to the benefit of both patients and industry. Under the PPRS, the UK operates a policy of freedom of pricing for new active substances at market entry, which, in contrast to many other countries that require price negotiations before entry, allows innovative drugs to be introduced into the market immediately after they have received a licence. Furthermore, NICE has made a significant contribution to the uptake of new drugs since its creation in 1999, through providing internationally respected guidance to the NHS on the clinical and cost-effectiveness of available drugs for a large number of conditions. A specific funding direction is in place which gives PCTs a statutory duty to provide funding for the implementation of NICE appraisal guidance.

25. A recent report: *Cancer Reform Strategy: Maintaining momentum, building for the future – first annual report* published by the National Cancer Director showed that there had been a significant increase in the uptake of NICE approved drugs across the country as a whole, together with reduced variation in usage across Cancer Networks. Increases in overall usage from 2005 to 2007/08 were observed for 13 of the 14 NICE approved drugs that were investigated. For seven of these drugs utilization has increased by 50% or more<sup>4</sup>. Further reductions in the variation in usage of these drugs across cancer networks have also been observed for nine of the 13 NICE approved drugs.

26. However, the Government fully acknowledges that further progress can be made in promoting the uptake of cost-effective new medicines, and believes that measures should be introduced to further increase patient access to these drugs and better reward companies for their innovation. Whilst, introduction of patient access schemes has already increased patient access to cost-effective innovative medicines, the Government recognised that further action was also required.

27. Increasing uptake of innovative clinically and cost-effective medicines was an important theme of the *Next Stage Review. The NHS Constitution* sets out two patient rights in this area. Firstly, patients have now been given the right to have access to drugs and treatments that have been recommended by NICE for use in the NHS, if the patient's doctor says they are clinically appropriate. Primary care trusts (PCTs) are normally obliged to fund NICE technology appraisals from a date no later than three months from the publication of the appraisal. The second right allows patients to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment the patient and their doctor feel would be right for them, the PCTs will be obliged to explain their decision.

28. Whilst previous PPRS agreements already had an R&D allowance and contained provisions to recognise innovation, the OFT presented a valid challenge on whether the PPRS promoted innovation sufficiently. Therefore, for the first time in its 50 year history, the PPRS included an innovation package. This package seeks to reward the development of innovative drugs

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<sup>4</sup> (trastuzumab, oxaliplatin, docetaxel, temozolamide, topotecan, vinorelbine and capecitabine)

by encouraging uptake through measures such as a new horizon scanning process, of new uptake metrics and the piloting of prescribing incentive schemes. The establishment of a single horizon scanning process for new drugs in development, with more systematic industry involvement, is envisaged to support better forward planning. If new drugs can be identified and clinicians informed of their potential benefits at an early stage, the NHS can be in a better position to ensure that these drugs are prescribed to patients when they need them.

29. The Government will also seek to work with relevant parties in the development of new metrics for the uptake of clinically and cost-effective medicines, starting with a number of drugs positively appraised by NICE, and the publication of comparative international data. National Cancer Director Professor Mike Richards' reports on uptake of cancer drugs, outlined earlier, have identified the importance of comparative information in improving uptake. Work to develop and understand the causes of international variations in drug use will be taken forward jointly with delivery of a related recommendation in *Improving Access to Medicines for NHS patients*, published in November 2008, under the leadership of the National Cancer Director. The Government will also work with PCTs to pilot the use of prescribing incentive schemes to promote the uptake of innovative products.

30. The PPRS innovation package can be read in full at [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH\\_091825](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH_091825). The inclusion of an innovation package as an integral part of a PPRS agreement for the first time demonstrates the Government's commitment to promoting uptake of innovation and the realisation of associated benefits for patients. NICE has also announced an independent study of value in new innovative health technologies on 27 January 2009. The study will involve submissions and the use of a series of workshops involving the healthcare industries, patients and the wider public, together with representatives of the NHS to explore this issue. These measures, together with the introduction of flexible pricing, should assist and encourage industry in the development of innovative new medicines.

### **Provide stability, sustainability and predictability**

31. The OFT report raised the vital issue of providing stability in the UK market in order to attract investment into the UK market. The PPRS has been a key part of this stability along with a number of other Government initiatives such as the Ministerial Industry Strategy Group (MISG), which provides a forum for industry to raise issues of concern with high level Government Ministers and officials.

32. The Government agrees with the OFT that in order to help the NHS and the pharmaceutical industry develop sustainable financial and investment strategies, the UK must remain a stable and predictable market that does not place unforeseen burdens on either party over the coming years. That is why the 2009 PPRS is a non-contractual voluntary agreement, designed to provide stability and predictability in pharmaceutical pricing for the NHS and industry for the next five years.

## **Devolved Administrations**

33. The Devolved Administrations have been involved throughout the processes and will continue to work with the industry on making progress in these areas of uptake and administration, and working with the Department of Health in England, where appropriate.

## **Medicines distribution – costs arising from changing distribution methods**

34. In December 2007, OFT published its market study into medicines distribution in the UK. The market study considered the potential impact of manufacturers introducing direct to pharmacy (DTP) schemes and/ or reducing the number of distributors they use. The study found that there is a significant risk that such arrangements will result in higher costs to the NHS potentially running into hundreds of millions of pounds and that such scheme could affect service to pharmacies and patients through for example longer waiting times to receive medicines.

35. The Government response was that the report was timely in that it gave the Government the opportunity to consider how to address the impact on costs through the negotiation of the PPRS. It agreed that the recommendations made by OFT should be discussed as part of the current PPRS negotiations and with other representative bodies of pharmaceutical wholesalers and pharmacy contractors. It was however, unconvinced of the need to bring forward legislation to clarify service standards at that time, but decided to keep the matter under review.

36. The impact of costs was reflected in the new PPRS through a provision for any scheme member which intends to change its overall distribution arrangements in a manner likely to increase costs to the NHS being required to notify the Department of Health in advance of such changes. The Department and the relevant company will discuss and agree any adjustments to distribution arrangements if changes have or are expected to have an adverse net impact on NHS expenditure. The Department of Health will also use the quarterly information it receives on discounts to monitor the impact of changes to the supply chain.

## **Conclusion**

37. The OFT report effectively challenged the Government to ensure that the PPRS delivered on a number of fronts and informed the recent renegotiation of the 2009 PPRS. The 2009 PPRS is expected to deliver important outcomes as a result. Delivery against these expectations sets the context for future schemes when the PPRS is due for renegotiation. Delivery will be monitored through formal meetings between the Department and ABPI, whilst certain elements of the new PPRS such as flexible pricing and patient access schemes will be subject to a review within two years. Delivery of the innovation package will be monitored through the Ministerial Industry Strategy Group (MISG). The Department will also be publishing PPRS reports to

Parliament. These arrangements will ensure that the 2009 PPRS remains fit for purpose.

38. In summary, the 2009 PPRS ensures that value is better reflected, delivers value for money, assists the uptake of innovative cost-effective treatments, rewards innovation and provides stability, sustainability and predictability. This will mean that NHS patients will benefit from innovative medicines at a fair price to the public purse and the pharmaceutical industry will continue to be encouraged to develop important new medicines. It is complementary to the work to develop a strategy for the life sciences sector being taken forward by the new Office for the Life Sciences (OLS) together with MISG involving the ABPI, Bio-Industry Association (BIA) and their members. This new balanced agreement therefore benefits the NHS, industry, UK PLC and most importantly patients and the public, leading to better health outcomes and improving quality of life.