Department of Health

Consultation on Revisions to the Statutory Scheme to Control the Prices of Branded NHS Medicines

June 2013

Published to gov.uk, in PDF format only.

www.gov.uk/dh

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Chapter 1 Introduction

Pharmaceutical Price Regulation Scheme

The Pharmaceutical Price Regulation Scheme (PPRS) is a voluntary agreement made between the Department of Health, on behalf of the UK Health Departments, and the branded pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry (ABPI). The PPRS puts in place controls on the prices of branded drugs sold to the NHS. It seeks to achieve good value for money for the NHS, whilst recognising that the industry needs to be profitable commensurate to value to enable it to develop and market new and improved medicines.

The PPRS covers all licensed, branded, prescription medicines sold to the NHS. It does not cover products without a brand name (generics) nor branded products available without prescription (over the counter (OTC) medicines) except when prescribed.

The PPRS was last negotiated in 2008, with the current scheme coming into force on 1 January 2009 for a period of five years. Notice of termination of the scheme was given in December 2012, and negotiations are now underway on a successor scheme, which will operate from 1 January 2014.

Statutory Price Control

In 2008, the Department of Health consulted on the introduction of regulatory provisions to put in place statutory price controls on the sales of prescription only, branded drugs to the NHS which were not covered through participation in a voluntary PPRS agreement. Unlike the PPRS, it was not proposed that prescribed OTC drugs would be covered. The purpose was to safeguard the financial position of the NHS by ensuring that:

- Some price controls continued to operate after the termination of the 2005 PPRS on 31 August 2008 and until a new PPRS was agreed; and
- Once a PPRS scheme was agreed, for any companies that decided not to join there would still be some control on the prices they charged.

As established when the statutory scheme was originally introduced, in the event of there being no voluntary agreement in place between the Government and the ABPI in the future, all companies selling branded medicines to the NHS would fall under the statutory provisions.

The requirements for this statutory scheme were set out in The Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008, which also amend The Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007. These are available at:

www.legislation.gov.uk/uksi/2008/3258/contents/made
www.legislation.gov.uk/uksi/2007/1320/contents/made

The principal elements of the statutory scheme as set out in these regulations include:

- Establishing a maximum price which can be charged for the supply of a specific drug, and making provision for adjustments to this price;
- Setting out the information which companies are required to provide to enable price control mechanisms to operate;
- Providing for certain exemptions to elements of the scheme in relation to low cost presentations; and
- Setting out provisions to cover the enforcement of the scheme.

Value-Based Pricing

The Coalition: Our Programme for Government outlined the Government's commitment to move to a system of value-based pricing (VBP), after the current voluntary branded medicines pricing scheme, the 2009 PPRS, ends. Through VBP, our priority is to give NHS patients better access to effective and innovative medicines at prices that reflect the value, in terms of clinical benefit and societal benefit they bring. Negotiations are currently in progress on successor arrangements to the 2009 PPRS. In March, the Government confirmed that NICE would be responsible for the full value assessment of new medicines as part of VBP. At the same time as publishing this document the Government is also giving NICE Terms of Reference for this work, and remain committed to introducing VBP for new branded medicines covered by both the voluntary and statutory pricing schemes from January 2014.

Context

The Government is committed to building on the UK's strengths, to ensure that it remains a global hub for the health life sciences sector. Following consultation with industry, in December 2011 two papers were published; the *Strategy for UK Life Sciences* and *Innovation, Health and Wealth* (IHW). These set out the Government's approach for supporting UK life sciences and promoting the uptake of innovation by the NHS.

The *Strategy for UK Life Sciences* is a long-term strategy, which aims to strengthen the life sciences ecosystem by supporting collaboration between academia and industry, improve the business environment for the sector and ensure a healthy skills pipeline for the future. A *One Year On* document was published in December 2012, setting out progress to date.

Innovation, Health and Wealth (IHW) seeks to overcome barriers to innovation that have built up over decades, and aims to deliver long term, sustainable change embedded right at the heart of the NHS. It sets out actions to reduce variation in the uptake of cost effective innovation in the NHS, to improve transparency around adoption and spread, and to create a system to deliver innovation. The newly formed Academic Health Science Networks (AHSNs) which bring together NHS and academic stakeholders with industry partners, are the main means through which we will accelerate the adoption of innovations in the NHS. The effective adoption and diffusion of innovation is key to securing better patient outcomes within the current fiscal environment.

In December 2012, Creating Change – IHW One Year On was published, and outlined that the milestones in IHW are all being delivered, although there is still more to do to spread best practice and new approaches throughout the NHS.

IHW committed the NHS to a range of actions to deliver rapid and consistent implementation of NICE Technology Appraisals throughout the NHS. There are now two published Innovation Scorecards. These measure NHS uptake of medicines and demonstrate any variation which can be acted on.

Measures have also been put in place to streamline the regulation of clinical research, open up anonymised NHS data to researchers via a world-leading data intermediary service (the Clinical Practice Research Datalink or CPRD) and incentivise NHS institutions to become better at supporting research including commercial research. Other achievements include:

- CPRD is already being used by commercial researchers to scope, plan and set up clinical trials;
- Recruitment of patients into clinical trials by NHS Providers with new National Institute for Health Research (NIHR) research contracts is being monitored and real financial incentives are in place to improve trial initiation. The 70-day benchmark for trial initiation, including recruiting the first patient into trials, has been put in place and performance will affect NIHR funding to providers of NHS services from 2013;
- NIHR has established two NIHR Translational Research Partnerships which are bringing together life sciences companies, NHS Trusts and universities and other research institutions in collaborative projects; and
- Numbers of NHS patients being recruited into clinical trials continue to increase: more than 630,000 participants were recruited to studies supported by the NIHR Clinical Research Network in 2012/2013 - a 7% increase on the previous year.

The announcement of the intention to sequence 100,000 genomes, made in December 2012, has undoubtedly given a strong signal of the UK's determination to retain a leading position in this sphere, and has been widely welcomed by pharmaceutical and biotechnology companies alike. The view most commonly expressed is that linking this genomic data with anonymised clinical records will place the UK in a unique position globally, which should be a strong incentive to life science companies to continue investing here.

Chapter 2 Revising the Statutory Scheme

With the renegotiation of the PPRS currently underway, it is timely to reassess the statutory scheme, and to consider how some of the elements of the statutory scheme might be adapted to work more effectively.

An important consideration has been to align the statutory provisions more closely to some of the core elements which currently apply as part of the PPRS.

The Government proposes to make several key changes to the statutory scheme to reflect the above. These include:

- Establishing revised reference prices;
- Introducing a new price adjustment;
- Removing the exemption to the price adjustment established by the £450,000 low cost presentation provision;
- Introducing a small firms exemption covering those with total UK sales of branded medicines to the NHS of less than £5 million;
- Introducing price controls on average selling prices within hospitals; and
- Making provisions for line extensions.

The Government intends to amend the existing regulations so that the new measures will come into force by 1 January 2014. Draft amendment regulations, which reflect these proposed changes and consolidate the existing regulatory provisions, are attached to further inform your response to this consultation.

Price Control

The basket of drugs against which the current statutory scheme provisions apply was established at 1 December 2008. As a number of new drugs have since come onto the market, the Government proposes that new ‘list price’ reference prices are established against an up to date basket of drugs. It is proposed that this will be determined from all drugs on sale on 1 December 2013.

It is also proposed that additional reference prices will be established to support the proposed introduction of price control on average selling prices (ASP) into hospitals. See the section on ASPs.

Price Adjustment

The downward price adjustment applied through the statutory scheme has been amended regularly to mirror changes in the price adjustment agreed through the PPRS. Negotiations are still underway on the PPRS, and no provisional agreement reached on the proposed price adjustment levels. The Government, therefore, is consulting on suggested price adjustments for the statutory scheme, with the intention that this will also inform discussions on the price adjustment during the PPRS negotiations.

The suggested levels for the downward price adjustment are:

- 10%
- 15%
- 20%

1) **Views are invited on the suggested levels of the price adjustment. Should this be the same as that agreed as part of the PPRS negotiations?**

Low Cost Presentations

Currently, where sales to the NHS of a given drug are no more than £450,000 in a calendar year, no price adjustment has applied. Instead, the price was capped at the reference price level, which was the price at which it was on sale at 1 December 2008.

However, the primary data source to check the level of NHS spend on a particular drug has historically been community pharmacy data, which primarily captures spend in primary care. Consequently, if a drug is sold mostly into secondary care it has effectively been exempt from the price adjustment.

Alongside the introduction of average selling prices (see below) the Government proposes that this low cost presentation provision be removed so that sales to hospitals are more effectively captured, and thus ensuring that the scheme more closely aligns to practice in the PPRS.

There is no intention to remove the low cost exemption relating to products costing less than £2.

2) **Do you think it is right that the £450,000 low cost presentation should be removed?**

3) **Are there any possible unintended or detrimental consequences which need to be mitigated against?**

Small Firms Exemption

Currently, where firms have sales of branded health service medicines of £25 million or more in England, they are exempt from the statutory scheme information provisions, though the price adjustment does apply.

However, the proposed introduction of price adjustments on average selling prices (see below) depends on companies supplying the information identified in the regulations. Consequently, the £25 million provision would provide a de facto exemption.

The Government proposes that this £25 million information exemption be removed, and replaced with an exemption which covers both the information requirements relating to average selling prices, and the price adjustment, for all companies with UK sales of branded health service medicines of less than £5 million. We believe this would ensure that there is no adverse impact on small firms, and would align to the existing small firm exemption in the PPRS.

4) **Do you agree that the £25 million information exemption should be removed?**

5) **Is the proposed £5 million small firms exemption needed?**

6) **Is the proposed small firms exemption set at the right level? Will companies be able to evidence that they are under this level without difficulty, either through audited company accounts, or documenting a quality assurance process?**

Average Selling Prices

In the current statutory scheme, the price adjustment is applied to sales in both primary and secondary care on the reference price, which is the list price of a given medicine as at 1 December 2008.

Typically, however, hospitals negotiate substantial discounts on drug list prices. These discounts will generally exceed the value of any downward price adjustment required by the statutory scheme, meaning that the price adjustment does not have any impact on prices paid by the NHS.

The Government proposes that the statutory scheme be revised to apply the price adjustment to Average Selling Prices (ASPs) in hospitals, aligning it to the general approach in the PPRS. The ASP is an average of the prices paid by all hospitals for a specific drug, taking account of all discounts negotiated with the supplier. Consequently, the price adjustment is in addition to any discounts. A calculation setting out in more detail how the ASP will be determined is set out in the attached draft regulations.

It is proposed that this calculation will be based on an additional set of reference prices, which for 2014 will be drawn from 1 October to 30 November 2013, and for 2015 onwards, will be drawn from 1 October 2013 to 30 September 2014.

To ensure that the necessary information is available to enable the application of a price cut to ASPs, some minor amendments to the existing information requirements as set out in regulations have been suggested. Primarily, the suggested changes require the provision of information on sale volumes for each presentation of a given drug, rather than aggregating by product. Additionally, the Government proposes to reduce the frequency of data reporting, so that companies only have to provide data annually, rather than every quarter.

The provision by companies of comprehensive, accurate information will be integral to the effective running of the statutory scheme. The Government proposes that information should draw upon audited data where this is available, and where this isn't possible companies should clearly demonstrate how their data has been quality assured.

7) **Do you agree with the proposal to apply the price adjustment to ASPs in hospital, aligning this more closely with the PPRS?**

8) **Does the suggested calculation accurately capture ASPs?**

9) **Are the suggested changes to the information requirements right, or would other information be needed?**

10) Do you agree that the proposed changes to ensure quality assurance of information are right? How might this best be put into practice?

Line Extensions

The Government proposes making provision in the statutory scheme for the handling of line extensions to a given drug, for example where a new presentation of a branded product is introduced, such as the introduction of a new capsule size or a different method of administration. The intention is to allow for the relevant reference price (i.e. the list price and the ASP) of the original presentation, and the price adjustment, to apply to these different presentations, which otherwise might not be captured within the scheme. We propose that this be managed through agreement between the relevant company and the Department of Health, taking into account wider industry practice in pricing line extensions, such as through the PPRS.

11) Do you agree that it is reasonable to incorporate line extensions?

12) Do you have any suggestions about how pricing decisions for line extensions should be made?

Penalties

The penalties schedule in the 2007 regulations is based on health service sales, which is determined by the most recent Annual Financial Return submitted by a company. To reduce burdens, the Government proposes replacing Annual Financial Returns as a determinant of penalty levels with total UK sales as determined by a company's most recent set of audited accounts.

13) Do you agree that the penalties schedule should refer to total UK sales as determined by a company's audited accounts instead of health service sales as determined by an Annual Financial Return?

Impact Assessment

An impact assessment (IA), which has been developed to identify the likely costs, benefits and wider impact of these proposed changes, accompanies this consultation. It also consider the impact of a 'no change' option. Your views are welcomed on the assumptions and analysis contained within the IA.

The impact assessment has 5 options: do nothing, apply a 10%, 15% or a 20% price cut and base the price adjustment on average selling prices rather than list price for sales into hospitals. This final scenario is based on a 15% downward price adjustment.

14) Do you agree with the assumptions and analysis on the costs and benefits of the proposed changes?

15) Do you agree that there will be no specific impact from the proposed changes on any particular groups, specifically those covered by the Public Sector Equality Duty?

16) Is it likely that the proposed changes will create any risks around continuity of supply of branded medicines?

Chapter 3 Responding to the consultation

You can respond to this consultation by post or by e-mail. You can send your response by hard copy to:

Statutory Pharmaceutical Pricing Scheme Consultation
c/o Stephen Lock
Room 456D
Skipton House
80 London Road
London
SE1 6LH

Or by e-mail to: Stephen.Lock@dh.gsi.gov.uk

The consultation closes on 31 July 2013.

Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please

contact Consultations Coordinator
Department of Health
2e08, Quarry House
Leeds
LS2 7UE

e-mail consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter.

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all

circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.