NHS England

Question and Answer document for the NHS on the Pharmaceutical Price Regulation Scheme (PPRS)

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What is PPRS?

The Pharmaceutical Price Regulation Scheme (PPRS) is a non-contractual voluntary scheme between UK Government and Industry covering all the relevant key issues that underpin the pricing of the majority of NHS branded medicines[1]. It runs for 5 years, and the most recent agreement was put in place on 1st January 2014. The agreement can be found here https://www.gov.uk/government/publications/pharmaceutical-price-regulation-scheme-2014

The PPRS is designed to strike a balance through promoting the common interests of patients, the NHS, the industry and the taxpayer. It encourages innovation and the development of high value treatments by promoting a strong and profitable pharmaceutical industry that is both capable of and willing to invest in sustained research and development. This encourages the future availability of new and improved medicines for the benefit of patients and the industry in this and other countries.

In what way is PPRS a "voluntary" scheme?

Pharmaceutical companies can decide whether they want to be a part of the PPRS scheme, but any company which decides not to be a member is automatically subject to the statutory scheme. The statutory scheme is set by DH, following consultation, and is subject to different terms. The statutory scheme in 2014 imposes a price cut on individual medicines of 15% of their NHS list price. The new PPRS scheme is different and sets a limit in growth on NHS spending for branded medicines sold in the UK by companies who have joined the voluntary scheme. DH has advised that 126 companies have joined the PPRS as of 1 January 2014 and a further 5 companies have expressed their willingness to join the scheme on 1 April 2014. These companies currently provide over 90% of branded medicines used by the NHS. A list of participating companies can be found here http://www.abpi.org.uk/our-work/commercial/pprs/Pages/default.aspx

What does PPRS do?

In previous years, the PPRS established a cut in list price for the branded medicines covered by the scheme (apart from new active substances launched during the course of the scheme). The NHS was then able to take advantage of these reduced prices.

This time, Government and Industry have taken a different approach. The 2014 PPRS continues to control the maximum prices and profits from the sale of branded medicines to the NHS. However it centres on an agreement to limit the

[1] Certain exclusions apply, including for SMEs

growth rate in NHS expenditure on branded medicines covered by the scheme. Growth in the branded medicines bill above the agreed level will result in a "PPRS Payment" being made by industry back to DH. The payments are based on the difference between the agreed forecast growth level and the allowed growth level. The estimated payment percentages are shown in Annex 3 of the agreement. Future payments will be adjusted if actual growth is above or below the agreed forecast. The detail of the agreement commits to an overall agreed allowed growth rate in the NHS branded medicines bill (subject to exclusions) of 0% for the next two years (compared with average 5% annual growth in the past) and then only a small growth rate after that, for the remaining three years of the Agreement.

There are a few exceptions where NHS expenditure on branded medicines covered by the PPRS are not included in the measured spend and do not count against the allowed growth rate. These include:

- exceptional central procurements out-with the normal annual pattern of NHS prescribing (such as national stockpiles for the security of the nation or pandemic preparation)
- parallel imports i.e. medicines which are imported and supplied to the NHS by a party other than the scheme member or a company that is affiliated to the company such as a parent company
- Companies with sales of less than £5 million in the previous calendar year will not be required to make payments to the Department. Their sales will not be included in the measured spend or count against the allowed growth rate

VAT costs are also excluded for the purposes of the PPRS agreement and associated calculations and payments.

Will the NHS be getting any additional funds as part of this agreement?

DH has already estimated the expected growth in the overall branded medicines bill, and the value of the PPRS payment they expect to receive from Industry. In respect of England, the anticipated payments in 2014/15 and 2015/16 have been passed on to NHS England through the Mandate. NHS England has already shared out these funds in the allocations to all commissioners as per the agreed allocations formula. In short, the NHS has already received additional funds related to the expected growth in the NHS branded medicines bill for 2014/15. Commissioners are free to invest their allocated funding to deliver improved outcomes as they see fit to meet local priorities for 2014/15. Similarly, indicative allocations for 2015/16 already take into account the expected PPRS payment.

How will the NHS benefit from the PPRS agreement?

In its broadest terms, the 2014 PPRS is a voluntary agreement to control the majority of NHS expenditure on branded medicines sold to the NHS by companies in the UK over the next five years. It also controls the overall profits

that pharmaceutical companies make through these sales to the NHS. The Health Departments in the UK and the ABPI have a common interest in ensuring that safe and effective medicines are available on reasonable terms to the NHS and in maintaining a strong, efficient and profitable pharmaceutical industry.

The NHS is not a signatory to the PPRS Agreement, but does have a keen interest in how to make the most of its implementation. NHS England is currently working with DH and ABPI on behalf of all commissioners to support the implementation, in a way that will enable the appropriate use of cost and clinically effective medicines to improve outcomes for all patients.

NHS England will provide more information on how we will work in partnership with Industry and NHS colleagues to support the implementation of the PPRS shortly. This is likely to focus on ensuring patients can access innovative medicines and can optimise the use of these medicines to get the best outcomes, and how the NHS, clinicians, other staff and services, and the Industry, can support patients to do that.

How do PPRS payments work?

A detailed explanation of the payment calculation formula is provided in Annex 5 of the PPRS agreement. In essence, if NHS expenditure was to go above the agreed growth rates in branded medicines, offsetting industry payments would be made to DH which under the PPRS are phased over the remaining years of the agreement. So, for example, if the actual NHS spend were to exceed the agreed growth rate of 0% for 2014 and 2015, then industry would make PPRS payments to DH on a quarterly basis. Each year the payment percentage for the following year will be adjusted based on previous years actual sales and modified estimates of the future trend. The actual sums paid are complex to calculate, due to re-forecasting effects.

Alternatively, if the NHS expenditure on branded medicines were to be below the anticipated forecast growth rates, then there would be a similar downward correction to the profile of future industry payments. In effect the industry would have been paying excessive quarterly payments to DH and these would be offset through reduced payments over the remaining years. In year 5, if there is any difference between actual spend and anticipated spend, there is no mechanism to address the difference.

Does the agreement mean that branded medicines covered by the scheme effectively become "free of charge" to the NHS after a certain point?

The NHS and pharmaceutical industry have a mutual interest to ensure patients can access clinically and cost effective innovative medicines and can optimise the use of these medicines to achieve better outcomes. The PPRS agreement includes a provision to the effect that all parties will operate the scheme in good faith and not seek to abuse it. It is important to note that the agreement makes no provision for what happens to the PPRS payments, so there is no

commitment for DH to make any additional payments to the NHS. Also, the agreement does not amend the established financial mechanisms in place in the NHS, such as the need to achieve financial balance within year, use of tariff etc.

Advice at this stage is that commissioners have received the expected level of funding to cope with growth in the cost of branded medicines, in line with expected prescribing behaviours, but not to view some medicines as becoming "free of charge" with more intensive use.

What impact should PPRS have on commissioning/prescribing decisions?

Prescribers and commissioners should continue to prescribe in a clinically and cost effective manner, ensuring that innovative and clinically cost effective medicines are made rapidly available to patients who need them. Allocations for 2014/15 have taken into account the anticipated growth in the branded medicines bill, so provision has been made in baseline allocations to allow prescribers and commissioners to continue improving uptake of NICE technology appraisals and delivering on Innovation, Health and Wealth.

Advice for 2014/15 is that commissioners have received the expected level of funding to cope with growth in the cost of branded medicines, in line with expected prescribing behaviours. The focus should shift from cost-saving onto securing better patient outcomes and value through medicines optimisation and commissioners should disengage from cost-containment measures that will not ensure value for money or patient benefit for the system as a whole.

This does not override the requirement to control expenditure within the annual budget. Nor does it override the requirement to comply with EU and UK law on procurement and competition, including, for example, promoting generic prescribing as usual.

Follow-up contact for further queries: England.pprsqueries@nhs.net