

NHS ENGLAND – BOARD PAPER

Title: Update on new voluntary medicines pricing scheme
Lead Director: Matthew Style, Interim Chief Financial Officer
Purpose of Paper: This paper provides an outline of the new voluntary medicines pricing scheme. The Heads of Agreement for the new scheme have been agreed between government, NHS England and ABPI, on behalf of the pharmaceutical industry.
Patient and Public Involvement: Patients and the public have fed into government and ABPI, who were leading preparations for the negotiations. Once negotiations began, discussions were limited to those parties named in the Scheme.
The Board invited to: Note the outline of the new voluntary medicines pricing scheme

Update on new voluntary medicines pricing scheme

Purpose

1. The Heads of Agreement for a new voluntary medicines pricing scheme have now been agreed between government, NHS England and ABPI, on behalf the pharmaceutical industry. The new scheme is expected to be in place from 1 January 2019.
2. The Board invited to note the summary of the voluntary scheme, and the next steps for publication and implementation.

Background

3. In 2014 a Pharmaceutical Price Regulation Scheme (PPRS) was agreed between government and industry, to control branded medicines spend in the UK. The current deal is due to expire on 31 December 2018.
4. Since spring 2018, negotiations have been taking place between the Association of British Pharmaceutical Industry (ABPI), government and NHS England to agree the terms of a new voluntary medicines pricing scheme.
5. The Heads of Agreement for the new voluntary scheme have now been agreed between government, NHS England and ABPI. Negotiations continue on the details of the final agreement.
6. The full scheme document containing further operational detail is expected to be agreed and published at the beginning of December 2018, with the new scheme due to begin on 1 January 2019.
7. This new voluntary scheme has been developed in partnership with the pharmaceutical industry. It is designed to support innovation, as well as manage expenditure on medicines, and will run for five years to 31 December 2024, operating alongside the statutory scheme to control the cost of branded health service medicines.
8. Companies that chose not to join the voluntary scheme will automatically be enrolled in the statutory scheme. The statutory scheme was updated in April 2018 so that companies repay a percentage of their eligible sales, rather than having a mandatory reduction to their list prices.
9. The voluntary and statutory schemes are therefore now intended to operate in a broadly equivalent way, although the voluntary scheme includes measures to support innovation and is more responsive to changes in spending.

Progress to date

Description of new voluntary scheme

10. The voluntary scheme is intended to support maintenance of the overall UK branded health service medicines spend and to provide predictability for all parties. The scheme is also intended to achieve a balance between access to innovative new medicines and affordability of spending, while increasing health gain per pound spent on medicines.
11. The Heads of Agreement for the scheme is in two parts. The first part relates to agreed medicines pricing and access policy, which sets the medicines environment for the NHS in England.
12. In particular, the scheme sets out a number of important areas that demonstrate the government and NHS commitment to support the use of innovative and clinically and cost-effective medicines. If agreed in full, the scheme will:
 - Support more effective horizon-scanning and earlier engagement with companies;
 - More and faster NICE appraisals for new medicines including speeding up appraisal of non-cancer medicines to be in line with cancer medicine appraisals;
 - Commit to retain NICE standard threshold at current levels (£20k-£30k/QALY)¹;
 - Commit to develop and publish a commercial framework, including additional commercial flexibility to support access to new medicines; and
 - Support the uptake of the most clinically and cost-effective new medicines
13. The second part of the scheme sets out the mechanism that is designed to control scheme members' branded medicines sales in the NHS. Note that sales do not directly translate to NHS spending on branded medicines, as some elements of spending are excluded from sales, the biggest being VAT and wholesalers' margins.
14. The key features of the 2019 mechanism are expected to be as follows:
 - The new scheme sets an allowable growth rate in sales of NHS branded medicines by companies in the scheme. Any growth above that level is repaid by those companies through payment of a defined percentage of sales.
 - Measured spend on medicines will be allowed to grow up to 2.0% nominal in each year of the scheme. This figure compares to an average of 1.1% in the current scheme.
 - Issues with the previous cap mechanism have been addressed, to make the approach more comprehensive and predictable for both industry and the NHS.
 - Some flexibilities have been removed, particularly on price modulation² and brand equalisation³.

¹ As stated in NICE's 'Guide to the methods of technology appraisal', when considering opportunity cost NICE uses £20,000-£30,000 as the range of maximum acceptable ICERs (incremental cost effectiveness ratio) in standard technology appraisals <https://www.nice.org.uk/process/pmg9/chapter/the-appraisal-of-the-evidence-and-structured-decision-making>

² Price modulation was permitted in the 2014 PPRS, whereby companies could increase the list price of some products in their portfolio if balanced by a reduction on others.

³ Brand equalisation is defined in the 2014 PPRS as occurring "where a scheme member offers dispensing contractors, whether directly or through wholesalers, additional discounts or rebates on branded medicines that result in them dispensing their brand against a generic

15. This second part of the scheme is also expected to include specific measures designed to support innovation, with exemptions for new active substances (i.e. products), freedom of pricing at launch, and support for small businesses.
16. More detail on the areas covered in the Heads of Agreement has been published by the Department of Health and Social Care⁴.

Implications

17. The new voluntary medicines pricing scheme is designed to ensure that the branded medicines bill stays within affordable limits, while also supporting innovation and small companies, delivering growth in branded medicines spend as well as faster access and uptake of the best new medicines.
18. NHS England has welcomed the opportunity to play a constructive role in these negotiations, and has a shared ambition with government and the pharmaceutical industry to make progress in a number of areas, in particular in supporting truly transformative products to get to patients quicker, through better engagement and preparation across the system for their introduction, and through the use of additional commercial flexibility where it is needed.
19. The industry rebate from both the voluntary and statutory schemes will directly support frontline NHS services, with the full amounts flowing through into the NHS mandate. This will provide significant resource to support the sustainability of the settlement announced by the Prime Minister in June benefitting patients.

Next steps or timeline

20. The full scheme document is due to be published at the beginning of December, with the new scheme due to begin operation from 1 January 2019.
21. Work will shortly begin on implementation of the new scheme, including the development of a new 'commercial framework'.

Recommendations

22. The Board is invited to note the outline of the new voluntary medicines pricing scheme.

Author Helen Scott, Head of Medicines Access and Pricing Policy & Barny Leavers, Acting Head of Financial Strategy & Allocations

prescription where there is a competitor generic presentation available"
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/675465/The_pharmaceutical_price_regulation_scheme_2014.pdf

⁴ <https://www.gov.uk/government/publications/voluntary-scheme-for-branded-medicines-pricing-and-access-heads-of-agreement/voluntary-scheme-for-branded-medicines-pricing-and-access-heads-of-agreement>