

ABPI Briefing

The 2014 Pharmaceutical Price Regulation Scheme (PPRS)

The Pharmaceutical Price Regulation Scheme (PPRS)¹ is a voluntary agreement between the Department of Health (DH), on behalf of UK Government, and the Association of the British Pharmaceutical Industry (ABPI), on behalf of the entire UK pharmaceutical industry, regarding the supply of branded medicines to the National Health Service (NHS) across the four nations of the UK.

- *The 2014 PPRS came into effect on 1 January 2014 and runs for five years.*
- *The PPRS covers most branded medicines supplied to the NHS.*
- *134 companies, representing 93% of the UK branded market, joined the scheme.*

The austerity contribution

- Recognising the financial challenges facing the NHS, and as a contribution to an exceptional period of austerity, the pharmaceutical industry has agreed to keep NHS expenditure on branded medicines in the scheme flat for two years and within agreed levels for a further three years. The pharmaceutical industry will underwrite any further expenditure by the NHS within agreed boundaries.
 - *No growth in the branded medicines bill in 2014 and 2015;*
 - *Growth in 2016, 2017 and 2018 limited to 1.8%, 1.8% and 1.9%, respectively.*
- If the allowed growth rate is exceeded, companies will make quarterly retrospective cash payments based on their NHS net sales.
- There will be certain exclusions from the measurement of growth and from the payment, including procurements of centrally supplied vaccines and any exceptional central procurements.
- Sales of medicines launched after 1 January 2014 will be included in the measurement of growth but not in the calculation of individual company payments. This means the NHS will still receive payments in relation to growth in spending on new medicines, but – as a pro-innovation measure – new products will not be penalised.
- Companies with NHS sales below £5 million per year will be exempt from payments.
- Patient Access Schemes, whereby arrangements are made with NICE to offer medicines for appraisal using different commercial mechanisms than the published NHS list price for certain patient populations, can continue to be put in place.
- Companies which choose not to be part of the voluntary PPRS will be part of the Statutory Scheme which includes a 15% list price cut in 2014.

The role of NICE in appraising medicines

- NICE will continue to make recommendations on the use of medicines in the NHS on the basis of technology appraisals. NICE will not negotiate or publicly set or publicly indicate prices.
- Companies can request their products go through a NICE assessment.

1. <https://www.gov.uk/government/publications/pharmaceutical-price-regulation-scheme-2014>

- The basic threshold range used in the calculation of cost-effectiveness for NICE appraisals will not be changed for the duration of the agreement. The current basic threshold is £20,000-£30,000 per Quality Adjusted Life Year (QALY) gained. NICE will continue to apply discretion in its application of the QALY, which currently results in some medicines, such as end-of-life medicines, being approved above that level.
- NICE will apply a broader definition of the value of medicines into its assessments. The process for building a broader perspective of value into the assessment of medicines will be subject to a pending public consultation by NICE before changes are implemented.

Patient access to innovative medicines in the NHS

- The Government will have surety and predictability around the bill for branded medicines in the NHS for the coming five years. The PPRS should go hand-in-hand with action by the Government and the NHS to ensure patients have access to the most innovative medicines in the UK. The agreement provides an opportunity to fix the access problem so that NHS patients get the best quality healthcare they deserve.
- We hope that the Government and the NHS will demonstrate their active commitment to improving patient access to the latest treatments.
- This includes the commitment to the *Innovation, Health and Wealth* aims of promoting rapid adoption and diffusion of innovative medicines which has been re-stated in the NHS England Mandate.
- The NHS England Innovation Scorecard will continue to be published quarterly showing levels of patient access to a number of medicines.
- Tenders should not be a barrier to patients' rights to access NICE recommended medicines, a right which is stated in the NHS Constitution.
- We hope that the Government and the NHS will demonstrate their active commitment to improving patient access to the latest treatments.