



Consultation on Changes to the Statutory Scheme to Control the Prices of Branded Health Service Medicines

Executive summary

Introduction

- 1.1. The Secretary of State for Health has powers under the National Health Service Act 2006 to limit the prices of or profits from sales of medicines supplied to the NHS. These powers provide for the existence of a voluntary scheme made by the Secretary of State in agreement with the Association of the British Pharmaceutical Industry (ABPI). The current voluntary scheme is the 2014 Pharmaceutical Price Regulation Scheme ("PPRS"). The powers also allow the Secretary of State, after consultation with the ABPI, to make a statutory scheme for the purpose of limiting the prices of or profits from sales of medicines supplied to the NHS by companies that choose not to be members of the voluntary PPRS agreement.
- 1.2. Previous PPRS agreements put in place a series of price adjustments, which were in turn mirrored by the statutory scheme. The 2014 PPRS operates through a different mechanism. Instead of a reduction in list price, the scheme limits the growth in the branded medicines bill for products covered by the scheme. Companies in the scheme make payments to the Department to cover spend above the agreed growth level, with the payment set as a percentage of their net eligible sales. The agreed growth limits over the five years of the scheme from 2014 to 2018 are 0%, 0%, 1.8%, 1.8%, 1.9%.
- 1.3. The current statutory scheme operates through a cut of 15% in the maximum price of branded health service medicines on sale on 1st December 2013.

Challenges

- 1.4. The reason we are consulting on reform to the statutory scheme is to meet the following challenges:
 - The statutory scheme produces lower savings relative to the health service sales covered by the scheme than the PPRS and the gap is expected to widen;
 - We need to re-align the statutory scheme savings with the PPRS in order to promote a more level playing field between the two schemes and in order to encourage companies to remain in the PPRS;

- It is currently difficult to re-align the schemes because of the differences in the mechanisms used to make savings;
- There are challenges relating to price controls and enforcement which we need to address.

Proposals

1.5. We are therefore consulting on the following options, in order to ensure that the cost of branded medicines to the NHS stays within affordable limits:

Option 1: A further cut in maximum price.

Option 1a: A further cut in maximum price including new products.

Option 2: A percentage payment by companies replacing the existing price cut.

Option 2a: A percentage payment by companies including new products.

1.6. In order to align relative savings better with those from the PPRS, and to encourage companies in the PPRS to remain there and not join the statutory scheme, we need to consult on a range of price cuts of between 20% to 30% and on a range of payment percentages of between 10% and 17%.

Factors to take into account

1.7. These are the factors that the Department thinks should be taken into account:

- The challenging NHS financial position and the need to maximise savings;
- The need to keep the savings from the statutory scheme in broad alignment with those from the 2014 PPRS, and to encourage companies to remain in the voluntary PPRS;
- The cost of research and development which allows the industry to continue to develop new medicines that improve outcomes for patients.

1.8. The three factors are interlinked – aligning the savings from the statutory scheme broadly with those from the PPRS should meet the need to control the cost of branded medicines to the NHS while continuing to support investment in R&D.

Government's preferred option

1.8 The Government's preferred option is Option 2a, a payment system with the payment set between 10% and 17%, applying to new as well as old products. Our Impact Assessment shows that this is the best option in economic terms. It also has the following advantages over a further cut in maximum price:

- It would deliver the highest level of additional NHS savings of all the options, estimated at £113m in 2017/18;
- It would result in a fairer outcome for companies in the statutory scheme than setting a uniform cut in list price which affects companies differently depending on the discounts they offer;

- It provides the best way to encourage companies to remain in the PPRS and therefore to prevent costs falling on the NHS through companies switching to the statutory scheme, estimated at £620m over the period 2016 to 2018;
- It would deliver an objective the Government's consulted on in 2013, of limiting average selling price in secondary care, because the payment percentage is applied to total sales having first deducted discounts;
- It would avoid the problems of having two list prices for the same product associated with the protection of prices of procurement frameworks in place at the time the regulations are implemented;
- It would help companies to compete globally by providing stability in UK prices.

Smaller companies

- 1.9. We are proposing to retain the exemption from the regulations for companies with sales of branded health service medicines below £5 million a year. As the £5 million threshold applies to sales of UK branded health service medicines, and does not include other UK or global sales, we believe that many medium-sized to larger companies are already covered by the exemption.
- 1.10. We aim to keep complexity and administrative burdens to a minimum for all companies, and in particular for smaller companies.

Price limits

- 1.11. If we introduced a payment system following the consultation, there would still need to be control over maximum prices in order to avoid price inflation. We are proposing the following improvements in order to increase transparency:
 - Creation of a published list of maximum prices which covers all medicines in the statutory scheme and the PPRS;
 - Publication of regular updates of current maximum prices for all medicines in the statutory scheme and the PPRS;
 - A requirement for companies to give the Department at least 28 days' notice of the price of a product prior to launch and of the intended launch date;
- 1.12. We propose to retain the ability of the Department to agree price control exemptions or price increases where necessary to ensure continued adequate supply of essential medicines. We are proposing improvements, including setting out factors for the Department to take into account in making decisions on whether to agree a request for a price increase and enabling the Department to request information needed to make this decision.

Enforcement

- 1.13. In order to ensure that we can if necessary take effective enforcement action, we are proposing to allow the Department to apply the current levels of penalties in the 2007 Regulations:

- where a company publishes a price for a medicine that is higher than the maximum price held on the Department's list described above;
- where a company fails to give the Department at least 28 days' notice of the price of a medicine before launch and of the launch date;
- for breaches of the proposed new requirements for payments and/or information to calculate payments.

Public sector equalities duties and health inequalities

- 1.14. By generating greater savings for the NHS, the proposals should have a positive impact on groups protected by the public sector equality duties and on health inequalities, by improving overall affordability of drugs and supporting better access to drugs to patients, including by people with protected characteristics, who in some cases may have greater need for treatment.