



Department
of Health

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

Consultation on Changes to the Regulations
Underpinning the Statutory Scheme

September 2015

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

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Chapter 1 Introduction

Powers to limit prices and profits

- 1.1. The Secretary of State's powers to limit the prices of, or the profits accruing from, health service medicines, are set out in sections 261-266 of the National Health Service Act 2006.¹ These powers provide for the existence of a voluntary scheme made by the Secretary of State with the industry body (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 industry body (“the ABPI”) to make a statutory scheme for the purpose of limiting the prices of, or profits accruing from, the sales of branded health service medicines by companies that choose not to be members of the voluntary PPRS agreement.

Pharmaceutical Price Regulation Scheme

- 1.2. The PPRS is a voluntary agreement made between the Department of Health, on behalf of the UK Government and Northern Ireland,² and the ABPI. The PPRS supports the NHS by ensuring that the branded health service medicines bill stays within affordable limits. It aims to strike a balance to promote the common interests of patients, the NHS, the industry and the taxpayer.
- 1.3. The PPRS covers all licensed, branded, health service medicines supplied by members of the scheme. It does not cover:
 - sales of products on private prescription or other use outside the health service in the UK;
 - products without a brand name (generics);
 - branded products available without prescription (over the counter (“OTC”) medicines), except when these are prescribed.
- 1.4. In 2013 a new scheme (“2014 scheme”) was negotiated between the Department of Health and the ABPI. The 2014 scheme commenced on 1st January 2014 and ends on 31st December 2018³.
- 1.5. Over the five years of its operation, the 2014 scheme provides unprecedented certainty on the maximum the NHS will spend on branded health service medicines while continuing to provide timely access to medicines for patients. The vast majority of branded health service medicine spend remains flat for two years, followed by small increases of less than two per cent for the remaining three years. Companies that are members of the scheme make payments to the Department of Health to ensure that spending on branded health service medicines stays at the agreed level.

¹ www.legislation.gov.uk/ukpga/2006/41/contents

² The pricing of medicines is reserved to the UK Government, with the exception of Northern Ireland. Many other aspects of health policies, including those affecting the use and availability of medicines, are devolved matters.

³ available at www.gov.uk/government/publications/pharmaceutical-price-regulation-scheme-2014

Statutory price control

- 1.6. In 2008 the Government consulted on regulations to set up the statutory scheme, the purpose of which was to safeguard the financial position of the NHS by ensuring that there would be similar limits to the PPRS on the cost of branded health service medicines supplied by companies that decided not to join the PPRS.
- 1.7. The regulations governing the statutory scheme are set out in the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008 ['2008 Regulations']⁴, and the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007 ['2007 Regulations']⁵, as amended.⁶
- 1.8. The principal elements of the statutory scheme include:
 - Establishing a maximum price which can be charged for the supply of branded health service medicines, and making provision for adjustments to this price;
 - Setting out the information which companies are required to provide to enable price limiting 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.

Statutory scheme – 2014 and 2015 Amendments

- 1.9. In 2013, the Department of Health consulted on proposals⁷ to amend the 2007 Regulations and the 2008 Regulations. The 2013 Regulations came into force on 1st January 2014.
- 1.10. The amendments included a 15% reduction in the maximum price of branded health service medicines that were on sale on 1st December 2013.
- 1.11. The Department also consulted on proposals to apply price limits to average selling prices in secondary care, including line extensions. The Department acknowledged in the response to the consultation the complexities around this issue and decided to give these issues further consideration.
- 1.12. In 2014, the Department consulted on proposals⁸ for further amendments to the 2007 and 2008 Regulations, including a further limit in the maximum price of branded health service medicines that were on sale on 1st December 2013.

⁴ www.legislation.gov.uk/uksi/2008/3258/contents/made

⁵ www.legislation.gov.uk/uksi/2007/1320/contents/made

⁶ These Regulations have been amended by the Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2013 ['2013 Regulations']

www.legislation.gov.uk/uksi/2013/2881/contents/made and the Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2015 ['2015 Regulations']

www.legislation.gov.uk/uksi/2015/233/contents/made

⁷ www.gov.uk/government/consultations/revisions-to-statutory-scheme-for-pricing-branded-nhs-medicines

⁸ www.gov.uk/government/consultations/branded-medicines-controlling-prices

- 1.13. Following the consultation, regulations implementing new information requirements and making further technical changes were brought into force on 9th March 2015. The Department decided not to introduce an additional price cut given the information then available. The response made clear that the Government would keep under review the need for a further price cut.

Chapter 2 Challenges

Summary

- 2.1. The reason we are consulting on further 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 companies in the two schemes and in order to encourage companies to remain in the PPRS to deliver its agreed objectives of stability and predictability to the Government and the pharmaceutical industry;
 - It is currently difficult to re-align the schemes because of the differences in the mechanisms used to make savings and the differential effect that the statutory scheme price cut has on companies depending on the levels of discount they offer the NHS;
 - The current regulations leave the Department with challenges relating to price controls and enforcement which we need to address.

Relationship to the PPRS

- 2.2. The key objectives of the PPRS are to support the availability and use of effective and innovative medicines for patients and to provide stability and predictability to the Government and the pharmaceutical industry. The PPRS gives pharmaceutical companies the certainty and backing they need to flourish both here and in the global market and keeps the branded health service medicines bill within affordable limits.
- 2.3. The purpose of the statutory scheme is to safeguard the financial position of the NHS by ensuring similar limits on the costs of branded health service medicines apply to companies that choose not to be members of the voluntary PPRS. Companies may move between the two schemes. The two schemes have different rules and different mechanisms for achieving savings on branded medicines.
- 2.4. In 2014 the statutory scheme covered around 6% of branded medicines sales in the UK – or around £710 million. This compared to £8,290 million – or around 75% of branded medicines sales – covered by the PPRS (there are exclusions from each scheme, for example parallel imports and wholesaler margins, which mean they do not together cover 100% of health service spend on branded medicines).
- 2.5. The current statutory scheme operates through a cut of 15% applied to the maximum price charged to the NHS on 1st December 2013 for a presentation on the market on that date. The maximum price is generally equivalent to the manufacturer's published NHS list price. In many cases, the NHS list price is higher than the actual price charged to NHS organisations due to discounts.
- 2.6. By contrast, the 2014 PPRS does not include cuts to the list price of medicines. Instead, companies make payments to the Department – calculated as a

percentage of their total branded medicines sales to the NHS (subject to certain exclusions and after deduction of discounts and Value Added Tax (VAT)).

- 2.7. Because the price cut in the statutory scheme applies to the published list price, and not the actual price paid by NHS organisations, the scheme produces lower savings in relative terms than the PPRS. Our modelling suggests that if the PPRS 2015 payment percentage of 10.36% applied to statutory scheme companies they would make payments of around £65 million, compared to around £23 million savings made through the 15% published list price cut⁹. This gap is expected to widen as the PPRS payment percentage responds to growth in drugs spend. The latest profile of PPRS payment percentages for 2016, 2017 and 2018 was 15% based on outturn growth in spend at end September 2014¹⁰.
- 2.8. In addition, there are no savings made in the statutory scheme on new products launched post December 2013. By contrast, spend on new products is included within the calculation of the PPRS payment percentages and reflected in the payments made by all PPRS companies against older products.
- 2.9. The PPRS stated¹¹ that the Department intended to consult on amendments to the statutory scheme to apply to companies that leave the PPRS to ensure that the price cuts applied to those members of the statutory scheme reflect at minimum the level of payment they would otherwise have paid in the PPRS.
- 2.10. As reported in the last consultation, we have concluded that developing provisions aimed specifically at companies that leave the voluntary scheme would be complex and might lead to undesirable behaviour. We do, nevertheless, consider it important to encourage companies to remain in the voluntary scheme in order to maintain the agreed objectives of the PPRS. This means that we need to consider how to re-align the statutory scheme broadly with the PPRS so that the savings made through the statutory scheme reflect at a minimum the savings contributed by companies in the PPRS. Such re-alignment is also necessary to promote a more level playing field for companies in either scheme.

Price limits

- 2.11. The Secretary of State may make Regulations to limit the maximum price that a manufacturer charges the NHS for a presentation. While the maximum price is generally understood to be the NHS list price, and is generally equivalent to the manufacturer's published price, there is no definition of NHS list price in legislation.
- 2.12. The NHS list price is used to inform the primary care reimbursement price paid to dispensing contractors and it is therefore important that the published price is not higher than the maximum price that has been agreed by the Department. In secondary care, medicines are procured by hospitals, often below the maximum price. While in most cases the manufacturer or supplier publishes an NHS list price which is within the maximum agreed under the regulations, in some cases the manufacturer either does not publish a price or chooses to publish a price which is different from the maximum price. There is therefore no definitive and publically

⁹ In order to make a fair comparison, this analysis ignores the effect of the protection of extant framework prices in the statutory scheme.

¹⁰ www.gov.uk/government/publications/pprs-payment-percentage

¹¹ Chapter 3, paragraph 3.12 of the 2014 PPRS

available list of maximum prices covering all presentations – either for the statutory scheme or the PPRS.

- 2.13. We consider that it is important to have more transparency regarding a presentation's maximum price. This will provide clarity with regard to the maximum price that a company may charge and in turn inform the primary care reimbursement price. It will also establish greater transparency with regard to maximum prices in secondary care. Among other things, this will also better enable the Department to monitor maximum prices and enforce any breaches of the maximum price.
- 2.14. Chapter 3 sets out a number of options for better aligning savings from the statutory scheme with those from the PPRS. Regardless of which option we decide to take forward as a result of this consultation, we need a transparent way of controlling the maximum price. As companies can choose to move between the statutory scheme and the PPRS, we consider that it is important that we have transparency on the price of a presentation on the reference date of the relevant scheme (1st December 2013 and 31st December 2013 respectively), and also have a transparent record of prices of new presentations and all other price changes to existing presentations that have come into effect since 1st December 2013, in order to contain the risk of price inflation.

Enforcement

- 2.15. While it is our experience that most companies cooperate with the Department and comply with the regulations, there may be rare occasions where there is non-compliance. The Department will always try and work with companies to secure compliance but it also needs to be fair, consistent and transparent in its implementation of the legislation. Therefore, in some cases, the Department needs to be able to challenge a company's non-compliance and demand appropriate penalties. The legislation allows a company to appeal to a tribunal against any enforcement action. We need to ensure that the enforcement provisions in the statutory scheme are fit for purpose.

Chapter 3 Proposals

Summary

- 3.1. In order to ensure that the cost of branded medicines to the NHS stays within affordable limits, we are consulting on the following options in order to better align the savings from the statutory scheme with those from the PPRS:
- Option 1:** A further cut in the maximum price of presentations on sale for health service purposes on 1st December 2013. We are consulting on a total cut of between 20% and 30%.
- Option 1a:** As Option 1, and also a cut in the maximum price on 1st September 2015 of presentations introduced for sale for health service purposes after 1st December 2013. We are consulting on a total cut of between 20% and 30%.
- Option 2:** Replace the current 15% price cut on presentations on sale for health service purposes on 1st December 2013 with a payment by companies against sales of such presentations, after first deducting discounts and VAT. We are consulting on a payment percentage of between 10% and 17%.
- Option 2a:** As Option 2, and also require a payment by companies against sales of new presentations on sale for health service purposes after 1st December 2013, after first deducting discounts and VAT. We are consulting on a payment percentage of between 10% and 17%.
- 3.2. More detail on each of the options for re-aligning the savings from the statutory scheme with those from the PPRS and the other proposals we are consulting on is set out below.

Aligning statutory scheme savings with those from the PPRS

Factors to take into account

- 3.3. In exercising certain powers under the National Health Service Act 2006 to limit the prices of, or the profits accruing from, health service medicines, the Secretary of State is required to bear in mind in particular the need for medicinal products to be available for the health service under reasonable terms and the cost of research and development (section 266(4)).
- 3.4. In view of this regulatory context, the factors that the Department considers should be taken into account, and which have informed our proposals, are as follows:
- The challenging NHS financial position. NHS England's Five Year Forward View¹² sets out the financial challenges facing the NHS and the need to maximise opportunities for savings.

¹² www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf

- 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.
- 3.5. 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. The objectives of the 2014 PPRS include keeping the branded health service medicines bill within affordable limits, improving access to clinically- and cost-effective medicines and supporting the Government’s growth and innovation agenda for life sciences. The 2014 PPRS aims to encourage 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 to encourage the future availability of new and improved medicines for the benefit of patients.
- 3.6. We are consulting on a range of price cuts between 20% to 30%. Our analysis shows that we would need a price cut of at least this level 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.
- 3.7. We are consulting on a range of payment percentages of between 10% and 17%. This is the level our analysis shows is needed to make broadly the same (relative) level of savings from the statutory scheme as from the PPRS, and to encourage companies in the PPRS to remain there and not join the statutory scheme.
- 3.8. Bringing the level of savings from the two schemes into better alignment would restore the situation that existed before 2014 when both schemes included a similar mechanism for controlling costs. Further detail is set out in the Impact Assessment which accompanies this consultation document. We will review the proposed price cut and payment ranges in the light of the responses to the consultation and also the adjusted PPRS Payment profile for 2016, 2017 and 2018, due to be published in December 2015.

Option 1: further price cut

- 3.9. Option 1 is to introduce a further limit to the maximum price of prescription only, branded health service medicines so that the maximum price which may be charged for the supply of a presentation would be the price at which that presentation was on sale for health service purposes on 1st December 2013 less between 20% and 30%, without regard to any discount or other variation in price which did not have general application on that date. In other words, the range consulted on is from 5 to 15 percentage points’ further downward adjustment in addition to the current 15% reduction in the maximum price.
- 3.10. Under this option, the current exclusions from the price cut set out in the statutory scheme would continue to apply:
- **Smaller companies.** The price cut would not apply to a company which has, during the most recent complete calendar year, supplied branded health service medicines for health service use in the UK, from which it derived a sales income of less than £5 million.

- **Over the counter medicines.** The price cut would continue to apply only to prescription only medicines. Including OTC products in the statutory price reduction would create significant operational difficulties for companies as they might need different pricing mechanisms for the NHS and other customers.
- **Low cost presentations.** The exemption from the price cut for presentations on sale for health service purposes on 1st December 2013 for a price of less than £2 would need to continue as a further price cut might lead to discontinuations or applications for price increases.
- **New products.** Under this option, there would continue to be an exclusion for presentations for which there was no price on 1st December 2013.
- **Extant frameworks.** The price cut in the 2013 regulations would continue not to apply to presentations procured under one or more framework agreements under the Public Contracts Regulations 2006 (as amended) that were entered into on or before 31st December 2013 and/or were entered into following a tender which closed on or before 31st December 2013. The additional cut in price of between 5 and 10 percentage points would not apply to presentations procured under one or more framework agreements under the Public Contracts Regulations 2006 (as amended) that were entered into on or before the date of coming into force of the additional price cut and/or were entered into following a tender which closed on or before the date of coming into force of the additional price cut.
- **Exemptions and price increases agreed by the Secretary of State.** Provisions equivalent to regulations 5 and 6 of the 2008 Regulations would continue to apply, subject to the proposals for improvements in those provisions set out below.

Option 1a: further price cut including newer products

- 3.11. In addition to introducing the further price cut on presentations on sale for health service purposes described above, Option 1a would introduce a limit to the maximum price of prescription only, branded health service medicines introduced for sale for health service purposes after 1st December 2013, so that the maximum price which may be charged for the supply of such a presentation would be the price at which that presentation was on sale for health service purposes on 1st September 2015 less between 20% and 30%, without regard to any discount or other variation in price which did not have general application on that date.
- 3.12. The current exclusions from the price cut set out in paragraph 3.10 above would continue to apply, except that the provision in regulation 3 of the 2008 Regulations (new products) would be amended to specify presentations where there was no price on 1st September 2015.

Option 2: payment system

- 3.13. This Option would require companies in the statutory scheme to make a payment to the Department of a percentage of their health service sales (having first deducted discounts and VAT and subject to the exclusions set out at paragraphs 3.16 and 3.17 below). Like the PPRS, this percentage would be set nationally, and paid

quarterly in arrears. The Department would take account of expected payments when setting NHS England's budget. As with the PPRS payments, the Department would ensure that all the income it receives from the payments in England is reinvested in the NHS for patients' benefit.

- 3.14. The percentage would be set in the Regulations following consultation. The aim would be to keep complexity to a minimum by simply setting a payment percentage aligned broadly with the PPRS payment percentage, rather than by including an equivalent to the PPRS Payments mechanism in the statutory scheme. Annex A sets out more detailed proposals on how the payment system would operate.
- 3.15. We are consulting on a payment percentage of between 10% and 17%. The payment percentage would be reviewed on an annual basis and, if necessary, adjusted in future following consultation.
- 3.16. We propose that companies with UK sales of branded health service medicines below £5m a year would be excluded from the payments.
- 3.17. The payment would not apply to sales of presentations procured under one or more framework agreements under the Public Contracts Regulations 2006 (as amended) that were entered into on or before and/or were entered into following a tender which closed on or before the date of coming into force of the new regulations.
- 3.18. There would need to be a limit on maximum price of a presentation (as with the PPRS) in order to avoid price inflation leading to a lack of transparency. It is proposed that the limit should apply to the maximum price on 1st December 2013 to bring the financial impact of the statutory scheme broadly into line with the PPRS. This would mean that companies would no longer be required to apply the 15% price cut. Companies would, of course, not be *required* to increase their prices and the price agreed under extant frameworks would not be changed. For products without a price on 1st December 2013, the limit would apply to the maximum price approved by the Secretary of State.
- 3.19. We envisage that there would be a continued need for provisions to allow for an exemption or an increase in the maximum price as set out in regulations 5 and 6 of the 2008 Regulations, subject to the proposals for improvements in those provisions set out below. However we propose that the exemptions under this regulation would apply to the limit on maximum price only. In line with the 2014 PPRS, we propose that companies should *not* be able to apply for an exemption from making the payments (either a blanket exemption or for sales of a specific presentation).

Option 2a: payment system including new products

- 3.20. This option would involve introducing a payment system as described above and also applying the payment percentage directly to the sales of new products.
- 3.21. Under the PPRS, although sales of new products (new active substances) do not attract PPRS Payments, the PPRS payment percentage applying to all other products is grossed up to take account of new product sales. However under the statutory scheme, the price cut only applies to products which were on the market at 1st December 2013. This leads to further inconsistency between the two schemes.

- 3.22. It would not be reasonable to expect the smaller number of companies in the statutory scheme affected by the regulations¹³ to pay a higher percentage on their older products to make up for the cost of new products (as happens in the PPRS where there is a much larger number of companies in the pool¹⁴). Therefore under Option 2a we simply propose not to exclude new products sales from the payment percentage. The percentage payment would apply to sales of both older and new products.

Government's preferred option

- 3.23. The Impact Assessment demonstrates that Option 2a, a payment system with the payment set between 10% and 17% and applying to new as well as old products, is the best option in economic terms. A payment system would also have the following advantages over a further cut in maximum price:

- It would deliver the highest level of additional UK savings from the statutory scheme 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. A cut in list price would inevitably affect companies differently depending on the profile of discounts they offer the NHS. Because a payment percentage applies to total health service sales having first deducted discounts, each company delivers the same level of savings relative to its sales income from NHS sales;
- It would deliver the closest alignment in terms of level of savings generated with the PPRS and therefore best support the aim of encouraging companies in the PPRS to remain there and not switch to the statutory scheme, thus mitigating the risk of additional costs to the UK NHS estimated at £620m over the period 2016 to 2018;
- It would deliver the Government's objective set out in the 2013 consultation of limiting average selling price in secondary care, because the payment percentage is applied against 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 extant frameworks. Sales of products under extant frameworks would be excluded from the payment, but the payment would not affect list price;
- It would help companies to compete globally by providing stability in UK prices.

- 3.24. Whichever option we decide to pursue following the consultation, we propose to revoke the 2007 and 2008 Regulations and replace them with a set of new, consolidated regulations. We propose that any new price adjustment or any payment percentage should come into effect no earlier than 1st April 2016.

¹³ At time of writing, twelve companies that are members of the statutory scheme are above the smaller companies threshold.

¹⁴ At time of writing 75 companies in the PPRS are above the smaller companies threshold.

Consultation questions

1. **We welcome views on the factors the Government should take into account when considering whether and to what extent further limits on the cost of branded health service medicines should be applied through the statutory scheme.**
2. **Comments are invited on the options set out above and the range of potential price adjustments or payment percentages.**
3. **Comments are invited on the detailed proposals for how a payment scheme might operate at Annex A.**

Smaller companies

- 3.25. Companies with sales of branded health service medicines below £5 million in the previous calendar year are exempt from the requirements set out in the statutory scheme regulations. 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.
- 3.26. In the last consultation, a number of companies highlighted the issue of the threshold “taper”. This was an exemption from price cuts for the first £5m of sales of companies with up to £25m of health service sales which was specifically available only to companies who were members of the 2009 PPRS and has never been available to companies who were covered by the statutory regulations.
- 3.27. Although referred to as a “taper”, the exemption still involved a cut-off point of £25m above which there was no exemption. This exemption was not included in the 2014 PPRS following negotiation of that scheme with the ABPI, the body that represented all of industry in the negotiations. The exemption for smaller firms in the statutory scheme is intended to align with that in the agreed PPRS and this continues to be a key objective in order to maintain the integrity of the branded medicines pricing system as a whole.
- 3.28. We propose that we should continue to apply the exemption from the requirements of the regulations to companies with sales of branded health service medicines below £5 million in the previous calendar year.

Consultation question

4. **Do you agree with our proposal that the threshold for the smaller companies exemption should remain as it is now, in line with the PPRS?**

Administrative requirements

- 3.29. The statutory scheme regulations are there to safeguard the financial position of the NHS by ensuring that there are similar limits as in the PPRS on the cost of branded health service medicines supplied by companies that decide not to join the PPRS. As it is a regulatory framework, the statutory scheme is less complex than the voluntary PPRS. We recognise that this administrative simplicity is valued by some companies that choose to be in the statutory scheme.
- 3.30. Therefore, while aiming to align the statutory scheme better with the PPRS in terms of level of savings, we would also aim to keep complexity and administrative

burdens to a minimum. Hence under Option 2 and 2a, we are proposing a simple percentage payment rather than seeking to reproduce the equivalent to the PPRS Payments Mechanism in the statutory scheme.

3.31. In the statutory scheme, we would not propose to carry across the following aspects of the audit arrangements from the PPRS:

- Tripartite audit engagements;
- The requirements to submit the audit plan;
- The mid-scheme reconciliation with administrative data.

Our proposals for sales reports and audit arrangements under a payment scheme are set out in Annex A. As part of this, we propose that companies under the £5m threshold in the statutory scheme should make an annual, unaudited return to the Department declaring their income from sales of branded health service medicines so that we can verify they are covered by the smaller companies exemption, just as in the PPRS. We need the ability to check whether those companies are eligible for the exemption and there is no other existing source for this information. However we are not proposing to introduce the requirements in the PPRS for a more detailed annual sales breakdown for companies with sales of branded health service medicines between £1m and £5m a year.

3.32. Again, to maintain administrative simplicity, we do not propose to introduce any new regulations providing for price modulation, flexible pricing or Patient Access Schemes (PAS) under the statutory scheme. These pricing flexibilities continue to be available within the relevant provisions to companies that are, or choose to, become members of the 2014 PPRS.

Consultation question

5. Do you have any comments with regard to our proposals to keep complexity of administration to a minimum?

Price limits

3.33. In Chapter 2 we described the need for a transparent and publically available list of maximum prices as there is currently no comprehensive, definitive list of maximum prices of presentations in either the statutory scheme or the PPRS. The National Health Service Act 2006 allows the Secretary of State to make a scheme to limit the prices that may be charged for branded health service medicines, including providing the Secretary of State with the power to request information. We propose to use these powers to compile the Secretary of State's own list of prices which would be published and updated regularly.

3.34. We propose to establish two lists. The first list would be an archived list of reference prices of all presentations in the statutory scheme and the PPRS on 1st December 2013 (the statutory scheme reference date) and on 31st December 2013 (the PPRS reference date). It is necessary to have the prices of presentations for both reference dates as a company can move between schemes; if it does then the reference date for the relevant scheme applies to that company's products.

3.35. We propose that the reference price list would be published. Most of the data will already be held either by the Department or by the NHS Business Services

Authority. We therefore do not expect this will lead to regular requests for information from companies, although there may be some occasions when we would need to request information.

- 3.36. The second list would be a current list of maximum prices which would be updated and published on a regular basis – we are proposing that this would be monthly. The list would be updated to include the maximum prices of all new presentations after 1st December 2013. In addition to providing accurate and current maximum price information, the list would be ready to serve as the new archive, reference price list for statutory purposes at a future date. We propose that the list should be updated to include:
- prices of new presentations (either new active substances or other new products);
 - approved price increases;
 - prices following maximum price exemptions;
 - PPRS modulated prices.
- 3.37. The PPRS requires companies to give the Department a minimum of 28 days' notice before the date of launch of a new medicine. In the PPRS, a company may not launch a medicine until it has received confirmation from the Department that it has freedom of pricing or that the proposed price is acceptable.
- 3.38. In practice, most companies in the statutory scheme adopt a similar practice, but currently the regulations do not stipulate this as a requirement. We propose, in line with the PPRS, to require companies to provide the Department with the proposed price of a new presentation at least 28 days prior to the launch date, together with confirmation of the date on which they are intending to launch the product.
- 3.39. We are aware of instances where a product has been marketed as a brand, and is subsequently marketed as a generic, either by the original supplier, or by the new supplier if sold on, and a large increase in price has been applied due to lack of regulatory control and lack of a competitive market for the product. This has an adverse effect on NHS budgets. We would welcome views on whether we should consider the options available to the DH such as Secretary of State's powers to limit the prices of health service medicines, for generic medicines such as these where there is no competitive market to secure value for money.

Consultation question

6. Comments are invited on the proposals to:

- **Create and publish on the Government's website an archive list of maximum reference prices which covers all presentation in the statutory scheme and the PPRS;**
- **Publish on the Government's website regular updates of current maximum prices for all presentations in the statutory scheme and the PPRS in a separate list;**
- **require 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;**

7. We would welcome views on whether we should consider the options available to the DH such as Secretary of State's powers to limit the prices of health service medicines, for generic medicines where there is no competitive market to secure value for money.

Exemptions and price increases

- 3.40. The 2008 Regulations include two separate provisions for price increases – regulation 5 and regulation 6. Both have the effect that the Secretary of State can, either on his own motion or following an application by a manufacturer, increase the maximum price of a presentation.
- 3.41. Regulation 5 allows for an urgent, temporary exemption from price controls to address imminent threats to continuity of supply. The provision can be applied to exempt suppliers/ manufacturers from the regulations in the 2008 Regulations relating to the control of maximum price, new products and the price limit on low cost presentations. We believe that provision of this nature is important in providing a flexible and rapid response to ensure continued adequate supply of essential medicines and that it should be retained.
- 3.42. However, the provision does not limit the level of the price increase and therefore a company could increase the maximum price beyond a price that is reasonable to mitigate the risk to supply. We therefore propose to include a provision in the regulations that would require the company to agree a temporary maximum price with the Secretary of State.
- 3.43. Regulation 6 enables a permanent increase in maximum price. When a company makes an application, it needs to state reasons for the application and the Department needs to respond within a specified time frame. As part of its application, the company has to submit audited accounts including figures for a number of cost factors including total profit (after interest charges and taxation).
- 3.44. However, the provision does not currently set out the factors which the Secretary of State will use to decide whether or not to allow an increase in maximum price. Also the information specified may not be adequate to underpin the decision. For example, the total profit of a company may not always be useful in order to evaluate whether an application for a price increase is justified.
- 3.45. We propose to retain a provision in line with regulation 6. However we propose that the new provision should (a) set out factors which the Secretary of State should take into account in making decisions on increases in maximum price and (b) enable the Secretary of State to request such information as he reasonably requires to make such decisions, including, but not limited to, the company's audited accounts for the latest accounting year and estimates for the two accounting years which follow. We are proposing that the factors that the Secretary of State should take into account should include, but not be limited to, the following:
- Whether the price proposed is in line with the price of other presentations of the same medicine or comparable products;
 - Whether the price proposed is in line with the price charged by the company for the same presentation in other European countries;

- The clinical need for the medicine and in particular can the company provide evidence that the proposed price increase is required to secure essential supply;
- The price at which the presentation would break even and the estimated profit margin of the presentation over the lifetime of the licence under the current and the proposed price;
- The total profit of the company after interest charges and taxation;
- Additional costs or considerations specific to the presentation (for example, manufacturing, supply, R&D costs or costs of providing information on how to use the presentation).

Consultation question

8. Comments are invited on our proposals to:

- **Require the company to agree a temporary maximum price with the Secretary of State where a temporary exemption from price controls is permitted;**
- **Set out factors for the Secretary of State to take into account in making decisions on whether to agree a request for a price increase from companies and enable the Secretary of State to request such information as he reasonably requires to make this decision.**

Enforcement

3.46. The 2007 Regulations provide for penalties to be paid on demand for contravention of regulations regarding the supply of information. We are proposing some changes to the provisions relating to the penalties currently set out in the Schedule to the 2007 Regulations to extend the existing penalty regime to breaches of certain of the proposed new provisions and to make some improvements in how the penalties are applied.

Publishing a price above the maximum price

3.47. Above we have outlined our proposal for creating an archive list and current list of maximum prices, both of which would be published by the Secretary of State. Given the need to establish greater transparency of maximum prices in primary and secondary care, we are proposing that any company who has published a price for health service supply that is higher than the maximum price held on the Secretary of State's list will be in breach of the regulations and would be subject to a daily penalty, at the existing levels of penalties for breaches of the 2007 Regulations.

Failure to give notice of product launch

3.48. We are also proposing that a company who has launched a health service medicine without giving the Department 28 days' notice of the proposed maximum price and intended launch date for that product would be subject to a daily penalty at the existing levels of penalties for breaches of the 2007 Regulations.

Failure to make payments or supply information to calculate payments on time

- 3.49. Under our preferred option for aligning savings from the statutory scheme with those from the PPRS - a payment system - we would be requesting additional information to calculate the scheme payments. We propose that the levels of penalties set out in the 2007 regulations would be applied in a case where a company is late in providing either the information or the payment, or both.
- 3.50. In line with standard business practice, we propose that the company would be given 30 days after the end of the quarter to provide both the information and the payment – the failure to provide either or both within this time frame would constitute a breach of the regulations and the Department could enforce a daily penalty as currently provided for in the Schedule to the 2007 Regulations.

Calculation of penalty

- 3.51. The Schedule to the 2007 Regulations provides for a daily penalty for the first 14 days and a daily penalty for subsequent days at two levels, depending on the size of a company's health service sales calculated by reference to its total health service sales sold in the UK as shown in its most recent audited accounts or other quality assured information. The lower daily penalty for smaller companies for the first 14 days is £2,500 and for subsequent days £5,000. The higher daily penalty for larger companies for the first 14 days is £5,000 and £10,000 for subsequent days.
- 3.52. The lower level of daily penalties (either for the first 14 days or for subsequent days) applies where the company's health service sales are less than £100 million or more and the higher level of daily penalties where the company's health service sales are £100 million or more. We are not proposing to change the amount of the daily penalties, nor the two tier system for smaller and larger companies. However we have identified a need to amend the information on which the definition of a larger or smaller company is based.
- 3.53. If a company does not provide information about their health service sales, the Department would not normally be able to ascertain this from the company's audited accounts. We are therefore proposing that, in the first instance, the level of penalty (lower or higher) should be determined on the basis of the company's total UK branded health service medicines sales, where quality assured information on these sales is available to the Department. The lower level would apply where the UK branded health service medicines sales are less than £100 million and the higher level where they are £100 million or more.
- 3.54. However, where such information is not available we propose that the level of daily penalty should be based on the size of the company's total UK sales which are set out in the company's statutory published accounts. The lower level would apply where the company's total UK sales are less than £100 million and the higher level where the company's total UK sales are £100 million or more.

General

- 3.55. We are not proposing any other changes to the information requirements. We are also not proposing to make changes to the enforcement of the controls currently in the 2008 Regulations on prices charged for supply of presentations to the health service; the existing provisions regarding the recoverable sum will continue to apply.
- 3.56. Any company that is subject to enforcement action taken by the Department can appeal against the action. If the appeal is unsuccessful, and in case of continued

non-compliance and failure to pay the penalty, the payment or both, then any debt owed to the Department by the company as a result of its non-compliance would be enforceable in court.

Consultation question

9. Comments are invited on our proposals to include provision to allow the Secretary of State to apply the current levels of penalties in the 2007 Regulations:

- **where a company publishes a price for a presentation that is higher than the maximum price held on the Secretary of State's list;**
- **where a company fails to give the Department at least 28 days' notice of the price of a presentation prior to launch and of the intended launch date;**
- **for breaches of the new requirements for payments and/or information to calculate payments,**

and to establish the level of the penalty for breaches of the regulations by using a company's total UK sales, in cases where information on branded health service medicines sales is not available.

Public sector equalities duties and health inequalities

3.57. We have made an initial assessment of the implications of these proposals on groups protected by the public sector equality duties and on health inequalities. Given the proposals will affect all branded medicines, directly or indirectly, we see no evidence that there will be a detrimental impact on particular protected groups or on health inequalities. 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.

Consultation question

10. We welcome any comments, including any evidence, on how the proposals may affect groups protected by the public sector equalities duties and health inequalities.

Chapter 4 Responding to the consultation

Responding to the consultation

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

Statutory Pharmaceutical Pricing Scheme Consultation
c/o Cathleen Schulte
Ground Floor North
Wellington House
133-155 Waterloo Road
London
SE1 8UG

Or by email to: Cathleen.Schulte@dh.gsi.gov.uk

The consultation closes on 04 December 2015

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
2e26, 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.

Annex A: Detailed proposals on payment system

Introduction

1. This Annex sets out more detailed proposals for how a payment system might work in the statutory scheme.
2. The proposal is to require companies in the statutory scheme to make payments to the Department similar to the 2014 PPRS Payments, but in order to avoid complexity, without relying on the PPRS Payments Mechanism. The Department would set the payment percentage nationally and companies would pay it quarterly in arrears, as a percentage of their health service sales (net of all discounts and VAT and subject to exclusions set out in the regulations).

Presentations covered by the scheme as a whole

3. We propose to bring into line the definition of products covered by the statutory scheme as a whole with the definition in the PPRS chapter 3, paragraphs 3.14-3.19, in order to reduce the incentive to switch sales between schemes, subject to possible amendments to achieve sufficient legislative certainty. This would mean bringing within scope NHS prescriptions of over the counter (OTC) medicines, except for allowing DH discretion to exclude OTC sales where NHS prescription sales are below £50,000 (paragraph 3.18 of the PPRS). We would propose for the same reason to remove the exemption for low cost presentations in regulation 4 of the 2008 Regulations. The current reason for those exemptions is the operational difficulty for companies involved applying a price cut to such products, which would not be an issue in a payment system.

Sales covered by the payment

4. Unlike in the PPRS, there should be no need to define “Measured Spend”, “Growth Rate of Measured Spend” or “Allowed Growth Rate of Measured Spend” as the payment mechanism would not be included in the Regulations. The only definition required beyond “presentations covered” would be “sales covered by the payments”.
5. The definition of sales covered by the PPRS payments is set out in paragraphs 6.4-6.10 of the PPRS. There are certain exclusions:
 - Sales that relate to Brand Equalisation deals (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 prescription where there is a competitor generic presentation available).
 - The following central procurements:
 - 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);
 - Procurements of centrally supplied vaccines.

- Sales by smaller companies, defined as companies with Sales of Scheme Products of less than £5m in the previous calendar year.
- 6. We propose that the payment percentage under the statutory scheme should be applied to sales of all presentations covered by the scheme, with a more limited number of exclusions than in the PPRS, as set out below.
- 7. We propose that sales that relate to brand equalisation deals should not be excluded from the statutory scheme payments. Such sales are difficult for companies to identify. If we included such an exclusion in the regulations, the onus would have to be placed on companies to show that brand equalisation as defined had occurred – i.e. that the product had been dispensed against a generic prescription, that there was a generic competitor available (i.e. a medicine without a brand name and not a “branded generic” of any kind), that the company had offered *additional* discounts beyond the norm for that product, and that as a result of those additional discounts the product had been dispensed against the generic prescription.
- 8. The rationale for excluding certain central procurements from the PPRS was that these sales would not be annual and would skew the growth calculation. As the statutory scheme would not embody the growth calculation then there would be no similar rationale for excluding such sales from the statutory scheme payments. We therefore propose not to exclude them.
- 9. Under the PPRS, companies do not make payments on sales of new products¹⁵, but the payment percentage for all companies is proportionately increased to cover the growth due to those products. It would not appear to be reasonable to introduce such a system in the statutory scheme as the impact of sales of new products would be very significant spread over the small number of companies which are currently affected by the statutory scheme regulations. Therefore, to keep the financial effect of the two schemes broadly in line, we propose that the payment percentage should simply be applied to sales of new products and that new products should not be excluded.
- 10. We propose that sales by smaller companies should be excluded from the payments. There would also need to be protection from the payment for sales of any presentation which was procured under extant frameworks.
- 11. We propose that the definition of sales covered by the payments would therefore be in outline:
 Sales of products covered by the scheme as a whole, net of all discounts and VAT, and excluding:
 - sales by any manufacturer or supplier who has, during the most recent complete calendar year, supplied branded health service medicines for health service use in the UK, from which it derived a sales income of less than £5 million;
 - sales of any presentation which was procured under one or more framework agreements under the Public Contracts Regulations 2006(a):

¹⁵ Defined in the PPRS as products introduced after 31st December 2013 following the granting of an EU or UK new active substance marketing authorisation from the appropriate licensing body. This does not include biosimilars or line extensions of products originally introduced before 31st December 2013.

- where the framework agreement was entered into on or before [the date of coming into force of the regulations] or was entered into following a tender which closed on or before [the date of coming into force of the regulations], and
- until the day after the day at the end of which the relevant framework agreement expires.

Payment percentage

12. We considered two options for setting the statutory scheme payment percentage set out below, of which the second is preferred:

- Adjust the payment percentage each year in line with the PPRS payment percentage for that year.
- Apply a fixed payment percentage in line with the expected PPRS payment percentage for 2018.

Option a. – adjust percentage each year

13. In order to deal comprehensively with the risk of switching from the PPRS to the statutory scheme, we would need to set the payment percentage in advance of each calendar year so that it was the same as the PPRS Payment Percentage for that year. However this would mean having to carry out a very short consultation on the percentage each year, as the PPRS Payment Percentage is announced in December and applies from the beginning of the following January. For this reason we do not advocate this option. We consider that setting a fixed percentage in advance would increase transparency and stability for companies in the statutory scheme.

Option b. – set fixed percentage

14. We are therefore proposing, for the sake of stability and transparency, to consult now on a payment percentage that applied to statutory scheme companies from 2016 onwards. We would need to review the percentage each year under Article 4 of the Transparency Directive. This would not necessitate a consultation on changes each year. However we could carry out a consultation if circumstances changed significantly, such that an alteration of the percentage was required.

15. Our current view (subject to the consultation) is that the percentage should be at least as high as the profiled payment percentage for the final year of the PPRS, as profiled in December 2015. Our current estimate is that this is likely to be between 10% and 17% based on the latest data on growth. Hence the proposed range consulted on.

Arrangements for making payments

16. We propose that each company covered by the statutory scheme and liable to make a payment (i.e. not covered by the smaller companies exemption) would make a payment each quarter to the Department of Health which is the percentage set out in the regulations, multiplied by the sales covered by the payment for that quarter. The payment and the accompanying quarterly sales report would be due within 30 calendar days of the end of each quarter. This would be similar to the arrangements for companies in the PPRS to make PPRS Payments. More detailed proposals on sales reports are set out below.

17. We are proposing that regulations introducing the payment system should be brought into force at the beginning of a calendar year quarter, and any changes to the payment percentage introduced in future (following consultation) should similarly apply from the beginning of a calendar year quarter.

18. However, given that we are not proposing to introduce a growth rate mechanism, it is not essential for the payment periods to align with the calendar year. In order to make it easier for companies to account for the payments and for the Department to verify the payments are accurate against the company's financial year annual statutory accounts, we are proposing that the payment period for a company should be the same as that company's financial year quarter.
19. If a company has financial year quarters that do not align to calendar year quarters, at the start of the system or at any point where the payment percentage changed, there would need to be provision to calculate payment due for a fraction of the company's financial year quarter pro-rata to the period of the quarter remaining when the new payment percentage applied. This would also be necessary to deal with a case where a company moved into the statutory scheme in the middle of a quarter.

Sales reports

20. New information requirements would be needed to support the proposed new statutory scheme payments. We are proposing that these should be similar to the PPRS sales reports requirements, but with some simplification to reduce regulatory burdens and administrative costs.
21. We propose that all companies in the scheme should supply the Department annually with a copy of their statutory audited accounts, within 9 months after the end of the company's financial year. We also propose that companies with UK branded health service medicines sales income of less than £5 million in the latest financial year, should make an annual, unaudited return to the Department declaring their income from UK sales of branded health service medicines so that we can verify they are covered by the smaller companies exemption, just as in the PPRS.
22. We propose that companies making payments (i.e. excluding companies benefitting from the smaller companies exemption) should supply the following sales reports:
 - Quarterly unaudited sales reports, due within 30 calendar days of the end of each quarter for which payment is due;
 - Annual audited sales reports and an independent auditor's report, due within 9 months of the end of the company's financial year, in respect of any financial year in which the company has made any payments.
23. The sales reports would need to be approved by a Director of the company. They would set out the sales covered by the payment for the relevant period net of discounts and VAT and show how those sales related to the company's management accounts (for quarterly reports) or statutory accounts (for the annual audited sales reports). Hence the reports would need to show sales net of discounts and VAT in the following categories:
 - Total company sales;
 - Total pharmaceutical sales;
 - Non- UK pharmaceutical sales;
 - Sales of presentations covered by the scheme as a whole;
 - Sales of presentations covered by the scheme as a whole in each exclusion category, separately;
 - Sales covered by the payment;

- Payment due.
24. We propose that the annual sales report should be audited under International Standards on Auditing (ISA) 805¹⁶ and according to the same materiality levels as required under the PPRS. Any error in any of the quarterly payments identified through the annual audited sales report would need to be corrected following the audit. Any amounts owed by either party would be settled in cash. As with the PPRS Payments, we propose to require that the annual sales report is audited by the auditor of the company's latest statutory accounts.
 25. As with the PPRS audit requirements, the Department of Health would have no liability for any fees in relation to the provision of the annual audited sales report. We would propose the audit report should meet the following requirements, at minimum:
 - In respect of the materiality used in the audit, this will be based on the materiality in the company's statutory audit, provided it is in the range of 0.5% - 1.2% of turnover. In the event that:
 - i. Materiality used for the statutory audit is in this range it can therefore be used.
 - ii. Materiality used for the statutory audit is above this range, 1.2% of Turnover is to be used (to ensure sufficient auditing of the Sales Report).
 - iii. Materiality used for the statutory audit is below this range, 0.5% of Turnover is to be used (to avoid expensive over auditing of the sales report).
 - The De minimis reporting threshold will be set at 10% of materiality.
 - The audit will evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates, if any, made by management; an evaluation of the overall presentation of the special purpose financial information including the assessment of the risks of material misstatement; and the reporting of any unadjusted errors.
 26. To keep regulatory burdens to a minimum we are proposing to omit the following aspects of the audit arrangements from the PPRS:
 - Tripartite audit engagements;
 - The requirements to submit the audit plan;
 - The mid-scheme reconciliation with administrative data;
 - The requirements for a detailed annual sales breakdown for companies with UK sales of branded health service medicines between £1m and £5m a year.
 27. In place of the detailed guidance and templates in Annex 7 of the PPRS, we propose to issue guidance and templates as required for companies in the statutory scheme.
 28. We propose to reserve the right for the Secretary of State to amend a sales report if he considers it to be inaccurate, taking into account relevant information on sales of UK branded health service medicines held by the Department or the health service. If a

¹⁶ Special considerations, audits of single financial statements and specific elements, accounts or items of a financial statement by the auditor of the company's latest UK statutory accounts.

company considered that the Secretary of State had calculated the payments due inaccurately, they could appeal to the tribunal.

29. The PPRS requires scheme members to provide unaudited presentation level sales reports within nine months of the financial year using the template at Annex 8 of the PPRS. This provides a further means for the Department to check the accuracy of PPRS sales reports submitted by companies. The statutory scheme already contains information requirements (for companies with sales over the £5m threshold) which were introduced in the 2014 Regulations to prepare for potential future introduction of limits on average selling price. Although we are not proposing to introduce limits on average selling price, we propose to leave the information requirements currently in regulation 3 of the 2007 Regulations (as amended) in place to fulfil the same purpose as the unaudited presentation level sales reports in the PPRS.
30. The provisions in regulation 3A of the 2007 Regulations (as amended) on information which may be required if there is a suspected breach of the price controls will continue to be needed for the price control provisions that would need to remain in place.