Department of Health

Government Response to the Consultation on Amendments to the Statutory Scheme to Control the Prices of Branded Health Service Medicines

Government Response to Consultation on Amendments to the Regulations Underpinning the Statutory Scheme

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Chapter 1 Introduction

Pharmaceutical Price Regulation Scheme

1.1. The Pharmaceutical Price Regulation Scheme (PPRS) is a voluntary agreement made between the Department of Health, on behalf of the UK Government and Northern Ireland and the Association of the British Pharmaceutical Industry (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.

1.2. 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.

1.3. In 2013 a new scheme was negotiated between the Department of Health and the ABPI and the 2014 PPRS commenced on 1 January 2014 (available at https://www.gov.uk/government/publications/pharmaceutical-price-regulation-scheme-2014).

1.4. The 2014 scheme provides greater certainty on the maximum the NHS will spend on branded medicines while continuing to provide timely access to medicines for patients. Under the 2014 scheme, the vast majority of NHS branded health service medicines spend will not change in the first two years of the scheme, followed by small increases of less than two per cent for 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.

Statutory price control

1.5. In 2008, the Department of Health consulted on the introduction of regulatory provisions to put in place statutory price limits on the sales of prescription only, branded health service medicines by companies that choose not to be members of the voluntary PPRS agreement. The purpose was to safeguard the financial position of the NHS by ensuring that there would be similar limits on the cost of prescription only, branded health service medicines supplied by companies that decided not to join the PPRS.

1.6. The Secretary of State's primary 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] Regulations setting out the requirements for the statutory

[1] http://www.legislation.gov.uk/ukpga/2006/41/contents

scheme are set out in the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008 ['2008 Regulations'][2], and the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007 ['2007 Regulations'], as amended.[3] These Regulations have been amended by the Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2013 ['2013 Regulations'].[4]

1.7. The principal elements of the statutory scheme as set out in these regulations include:

- Establishing a maximum price which can be charged for the supply of prescription only, 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.

Consultation

1.8. On 10 October 2014, the Government published the *Consultation on Amendments to the Statutory Scheme to Control the Prices of Branded Health Service Medicines*.

1.9. The consultation concerned options for:

- a further limit to the maximum price of prescription only, branded health service medicines with reference to the price at which the presentation was on sale for health service purposes on 1 December 2013;
- strengthening the information requirements for enforcement to enable fair and consistent application of the limit on price.

1.10. In the consultation document, we also said that we would be making two technical changes to the 2008 Regulations in order to clarify the position in respect of 'over the counter' medicines (where we intend to revert to the position prior to the 2014 amendments) and in respect of the application of the regulations to certain framework agreements tendered under European and UK procurement law. These were technical matters which did not form part of the consultation.

Responses

1.11. A total of 29 responses were received, of these 21 were from pharmaceutical companies and their trade associations, or consultants advising the industry. Other respondents included NHS organisations, one patient support group, one research

[2] www.legislation.gov.uk/uksi/2007/1320/contents/made6
[3] www.legislation.gov.uk/uksi/2008/3258/contents/made
[4] http://www.legislation.gov.uk/uksi/2013/2881/contents/made

charity and one private individual. Respondents to the consultation are listed at Annex A.

1.12. We are grateful to all those who responded to the consultation.

Roundtable meeting

1.13. As part of the consultation process, the Minister for Life Sciences and Department of Health officials met with companies who are impacted by the regulations for a roundtable discussion of the consultation proposals.

1.14. In this meeting, companies raised a number of wider issues concerning uptake and patients' access to medicines; some of these views were submitted in writing in response to the consultation. Although it did not consult on these issues, the Government is committed to encouraging the availability of innovative and clinically- and cost-effective medicines.

Chapter 2 Summary of key responses to the consultation questions and the Government response

Price adjustment

Question 1: We asked, "Comments are invited on the range of potential price adjustments."

2.1. We consulted on further limiting 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 1 December 2013 less 15%-25%, without regard to any discount or other variation in price which did not have general application on that date.

2.2. The consultation set out the factors which we would take into account when reaching the decision on a further price adjustment:

- the challenging NHS financial position in 2015;
- the requirement under the European Transparency Directive to carry out a review of the price cut;
- the unexpectedly high growth in the branded medicines bill;
- the need to align broadly the effect of the two schemes, while taking account of the differences between them;
- the importance of encouraging companies to remain in the voluntary scheme in order to maintain the stability and predictability of the PPRS;
- the cost of research and development.

2.3. Almost all respondents commented on this proposal. The majority (17) of industry respondents and their representatives were opposed to any further price reduction, while two companies supported it and two were broadly neutral. Other respondents, including those representing the NHS, were in favour of a price adjustment to ensure that the statutory scheme remained broadly aligned with the PPRS.

Question 2: We asked, "We welcome views on the above factors and any other considerations 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, for example the impact that any price adjustment might have on companies that are close to the £5m exemption threshold."

2.4. Respondents who were opposed to the price adjustment proposals submitted a range of views. The main arguments that were made against the price adjustment proposal were:

- A further price adjustment was arbitrary and there was no explanation of how growth in the branded medicine bill in the PPRS of 5.5% translated into a 25% price cut in the statutory scheme. Some argued that the schemes were too different from each other to be aligned;
- The proposal would lead to supply problems and withdrawal of essential medicines from the UK market;
- There would be an adverse impact on UK investment and growth of smaller companies.
- Impacts on international reference price;
- It would cause uncertainty – companies had chosen the statutory scheme because of its stability; and the proposals had also been announced at too short notice;
- A price adjustment would lead to possible destabilisation of PPRS through companies leaving the statutory scheme to join it;
- There was a view that savings from companies in the statutory scheme in 2014 were greater than the savings from companies in the PPRS and a question on whether and how these might be recovered if a company moved back into PPRS.

2.5. A number of respondents from industry, in particular those representing small and medium-sized companies, suggested that the statutory scheme regulations should include an exemption to the effect that companies with up to £25 million sales of health service medicines would be exempt from any price adjustment for the first £5 million of such sales (referred to as a "taper"). The main concern was that the £5 million threshold acted as a disincentive to growth to smaller companies and was unfair to companies who had sales just above the threshold.

Government response

General

2.6. On 11 December 2014, we published the PPRS quarter 3 net sales data and PPRS payment percentage for 2015. The data showed higher than forecast growth of the branded medicines bill throughout the first three quarters of the PPRS. The growth rate of the medicine bill covered by the PPRS payment (measured spend) was 5.93% (compared to the agreed forecast of 3.87%). This has resulted in a PPRS payment percentage for 2015 of 10.36% compared to the 7.13% estimated in the PPRS.

2.7. The Government recognises that the statutory and voluntary schemes operate via different mechanisms and we noted this in the consultation document. The statutory scheme price adjustment is applied to the maximum price which may be charged for the supply of a presentation, without regard to any discount or other variation of the price which did not have general application on that date. By contrast, the PPRS limits total eligible spend and the payments made by companies apply to net sales

after discounts have been applied, in addition to controlling prices and limiting profits.

2.8. Nevertheless, the Government's aim is to keep the two schemes in broad alignment. As set out in the Impact Assessment which accompanied the consultation document, it is possible to analyse the impact of the two schemes on companies, based on product portfolios. The Government needs to retain the flexibility to respond to stronger than predicted growth in NHS spend on branded medicines, leading to higher than forecast PPRS payment percentages.

2.9. Despite clear evidence of higher growth than forecast in quarters 1-3 of the PPRS, we have taken into account arguments in the consultation responses and decided that we will not introduce an additional price cut given the information we currently have. While the PPRS payment percentage for 2015 is now fixed, the payment percentages for 2016-2018 are still forecasted and will need to be adjusted year on year depending on outturn. The decisions of PPRS companies as to whether to enter the statutory scheme cannot be predicted with certainty as they depend on factors outside the NHS, such as possible "reference pricing" effects in other countries.

2.10. We will therefore observe developments in the two schemes during 2015 and will keep this issue under review as more PPRS data becomes available. We may need to introduce a further limit on maximum price in the statutory scheme during 2015 within the range set out in the consultation document in order to keep the schemes in alignment.

Supply

2.11. Many industry respondents commented that any further price adjustment would pose a risk to continued supply and that some companies may be forced to withdraw essential medicines from the UK market or that supply of medicines to the NHS may become economically unviable for the company. In particular, companies producing biotherapy products commented that these products, which are not protected by patents, have significantly higher production costs than synthetic pharmaceuticals and that a further price adjustment would threaten continued supply in the UK, as manufacturers would choose to supply their products to countries where they can demand a higher price. This concern was also shared by a patient group. A similar issue was raised by a company producing radioactive isotopes for medicines use.

2.12. Regulation 5 of the Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008 allows the Secretary of State to exempt a presentation from the price adjustment. Furthermore, Regulation 6 of the Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008, as amended, provides that companies can apply for an increase in the maximum price. The Government believes that these provisions offer the necessary protection to safeguard the continued supply of essential medicines to the NHS.

Research and development

2.13. A number of companies commented that a further price adjustment would act as a disincentive to pharmaceutical industry investing in research and development and that it would reduce the attractiveness of the UK as a location for investment. As we

have set out in the consultation impact assessment, in order to provide incentives for investment in research and development, medicines are permitted a period of exclusivity, during which they are able to gain high prices under the patent mechanism. Normal market forces do not operate during this period so Government must intervene to limit prices of branded medicines in order to safeguard the finances of the NHS and its ability to meet the health needs of the nation. We take the view that the impact of any price adjustment on global incentives for research and development (R&D) are likely to be insignificant.

2.14. The Government remains committed to ensuring that the UK is a world leading place for life sciences research and investment. We believe that the UK continues to be an attractive location for investment, as a result of initiatives such as the Patent Box and extending R&D tax credits as well as the UK's strengths in terms of R&D infrastructure and the availability of skilled staff.

Small firms exemption

2.15. A number of smaller companies highlighted the issue of the threshold taper. Currently manufacturers and suppliers with sales income from branded health service medicines of less than £5 million a year are exempt from making price adjustments and we are not proposing to change this exemption. 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 and do not need to make price adjustments.

2.16. The Department considers that it may also be helpful to clarify that the exemption for the first £5m of sales of companies with up to £25m of health service sales was specifically available only to companies who were members of the previous PPRS and that it has never been available to companies who were covered by the statutory regulations.

2.17. 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 industry 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.

Other comments

2.18. A number of other comments on issues relating to the price adjustment proposal were received. These included:

- Respondents representing the branded generics industry argued that any further price adjustment would have a particularly negative effect on branded generics as the market for branded generics was already highly competitive with low margins. A further price adjustment would make branded generics economically unviable and affect incremental innovation of these products. It was argued that branded generics should be exempt either from any further price adjustment or from the scheme altogether.

- Some argued that biosimilar medicines, which require a brand name, were already significantly cheaper than patented, originator products and that the increased uptake of biosimilars could deliver savings for the NHS.
- Some companies commented that a further price adjustment would affect their ability to conduct clinical trials in the UK and that it would impact on new medicine launches.
- One respondent expressed the view that the reference date in the regulations, i.e. the date from which any price adjustment is applied, should be brought forward to 1 December 2014.

2.19. With regard to branded generics, we note the industry's comments regarding these products. However, we do not believe that branded generics would be disproportionately affected by further price adjustments and we cannot offer branded generics protection over the originator product. Furthermore, if the supply of these products did become economically unviable, under Regulation 6 of the Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008, as amended, companies can apply for an increase in the maximum price.

2.20. Regarding medicine launches, products launched after 1 December 2013 are exempt from further price adjustments, we therefore do not believe that this would impact on medicine launches. We also do not agree that a further price adjustment would impact on a company's ability to conduct clinical trials and have not received any specific evidence of this.

2.21. We have noted the further comment on amending the reference date. This would result in the price adjustments applying to presentations launched after the current reference date of 1 December 2013 and up to the proposed new reference date of 1 December 2014. Although we did not consult on amending the reference date, the Government notes this proposal.

Uptake of and access to clinically- and cost-effective medicines

2.22. A number of respondents commented that, in their view, the price adjustment proposals were unhelpful to the UK pharmaceutical industry and undermined the Government's commitment to supporting the life sciences sector. Some also perceived a disconnect between the proposals and the Department's stated objectives of improving patients' access to clinically and cost-effective, innovative medicines, referring in particular to perceived barriers in NICE technology appraisals and uptake of NICE-approved medicines by NHS England as well as lack of progress with other innovation initiatives.

Government response

2.23. The PPRS has a balanced set of objectives that include ensuring that the branded medicines bill stays within affordable limits for the NHS and also improving patients' access to innovative medicines commensurate with the outcomes they offer patients. The Government is committed to ensuring that the UK life sciences sector delivers for patients, for their families and for the wider economy. Flowing from this

is the Government's continuing commitment to increasing the uptake of, and access to, clinically- and cost-effective medicines.

2.24. We therefore welcome NHS England's recent Five Year Forward View which sets out a commitment to supporting innovation – through a commitment to research, and to accelerating the quicker adoption of cost-effective medicines, diagnostics and devices.

2.25. To support these objectives further, on 20 November the Government announced a major new review that will specifically consider how to speed up access for NHS patients to cost-effective new diagnostics, medicines and devices.[5] The review will focus on innovative types of product: in particular, drugs based on stratified medicine, new diagnostics, and digital health technologies. The *Innovative Medicines and Medicines Technology Review* will start work early in the New Year, and will engage with patients, industry and regulatory organisations as it develops its recommendations. An independent organisation will be appointed to carry out the review which is expected to report later in 2015.

2.26. As a result of existing efforts to find opportunities to improve the adoption and diffusion of innovative medicines and health technologies, progress has already been made in supporting faster and wider patient access to clinically and cost-effective new drugs and treatments, for example through the Early Access to Medicines Scheme and the European Medicines Agency's Adaptive Licensing pilot.

2.27. As part of the 2009 PPRS agreement, the Department and the Association of the British Pharmaceutical Industry (ABPI) agreed to work together to develop metrics that compared the use of medicines recommended by NICE with the estimated number of eligible patients (where such an estimate could be produced by NICE). These metrics were published annually as the *Use of NICE-Appraised medicines in the NHS in England* report. The most recent report was published in January 2014.[6]

2.28. In addition, NHS England has developed *NICE Technology Appraisals in the NHS in England (Innovation Scorecard)* to track uptake of NICE technology appraisals. The aim of the Scorecard is to help the NHS to understand how the uptake of appraised medicines varies across England.

2.29. The current 2014 PPRS agreement sets out a commitment for the Department, NHS England and the pharmaceutical industry to 'work together to deliver a single transparent programme of activities looking at comparative medicines use in the NHS'. The latest *NICE Technology Appraisals in the NHS in England (Innovation Scorecard) to March 2014, Experimental Statistics* was published on 25 September 2014[7] and was the first step in bringing this work together, drawing in elements from the PPRS metrics work.

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[5] https://www.gov.uk/government/news/major-investment-in-life-sciences

[6] http://www.hscic.gov.uk/catalogue/PUB13413/use-nice-app-med-nhs-exp-stat-eng-12-rep.pdf

[7] http://www.hscic.gov.uk/catalogue/PUB15058

2.30. In addition, NHS England and the ABPI have formed a joint steering group, chaired jointly by the Chief Pharmaceutical Officer for NHS England and the Chief Executive of the ABPI and with representative membership from different parts of the sector, on maximising the benefits of the PPRS through 'medicines optimisation', i.e. a programme of action to create clinical pull in order to accelerate the uptake of innovative, clinically- and cost-effective medicines. Progress on this programme is reported quarterly to the Ministerial Industry Strategy Group who have agreed the following work areas for the programme, some of which cover delivery of the commitments outlined above:

- Developing the concept and approach to medicines optimisation;
- Utilising metrics to monitor access and uptake of innovative medicines;
- Exploring how Commissioning through Evaluation could be used to enhance the use of clinically- and cost-effective branded specialised medicines;
- A culture change programme aimed at winning hearts and minds.

2.31. We expect that the effects of the medicines optimisation programme will be felt widely across the NHS and will therefore benefit innovative, clinically- and cost-effective medicines supplied through both the voluntary and statutory schemes.

International variations in drugs usage

2.32. In order to make a valuable comparison of medicines use in the UK to that of other countries, the 2014 PPRS includes a commitment that 'NHS England and the Department will work together to develop and evolve an approach to the analysis and publication of comparative information on international medicines use on a periodic basis that incorporates this context, with a first report to be published by the end of 2014. A joint Department of Health, industry and NHS England working group will oversee this activity with a particular focus on NICE-approved technologies and with the objective of complementing parallel activity to understand domestic patterns of medicines use.' The commitment builds on Professor Sir Mike Richards' *Extent and causes of International variation in drugs usage report*, published in 2010.[8] This work has been completed and two reports published on 27 November.[9]

Strengthening the information requirements for enforcement

Question 3: We asked, "Should manufacturers and suppliers be required to record and keep information on actual selling prices of branded health service medicines in order to strengthen the Department's ability to enforce the scheme where necessary and support a fair and consistent application when necessary?"

[8] https://www.gov.uk/government/publications/extent-and-causes-of-international-variations-in-drug-usage

[9] by the Office of Health Economics [OHE] http://www.abpi.org.uk/our-work/library/industry/Documents/meds_usage.pdf and RAND Europe http://www.rand.org/pubs/research_reports/RR899.html

2.33. Just under half of all respondents, and the majority of industry respondents, were in support of the proposal. A smaller number were neutral in their comments on this question, and of these some were unsure or unclear of what the proposals meant and asked for more clarification on the need for the proposal. Four respondents, all from industry, were against the proposal, some of these also requested further clarification.

Question 4: We asked, "Do you agree that manufacturers and suppliers already record this information?"

2.34. Around a quarter of respondents did not answer this question. The majority of respondents from industry agreed that companies already record this information although some said it would depend on the detail and format of the information that is requested. A minority expressed concerns about the disproportionate effect the proposal might have on smaller companies.

Question 5: We asked, "Do you agree that manufacturers and suppliers should be required to supply this information on demand?"

2.35. Nearly all respondents from industry answered this question and most were in favour of the proposal. A small number of industry respondents disagreed, citing concerns regarding administrative or regulatory burdens for smaller companies and general resource implications. Some suggested that a reasonable notice period should be given. All respondents from other organisations, either did not comment or they supported the proposal.

Question 6: We asked, "Do you agree that penalties should be applied to these new information requirements?"

2.36. A smaller number of industry respondents (five) were in favour and some did not respond. Around a quarter of industry respondents were either against the proposal or said that the consultation should have provided more detail. Only a small number of non-industry respondents replied to this question, of these all were in favour of the proposal.

2.37. Overall, the main concerns expressed by industry in response to these proposals were that:

- The additional reporting was a concern and companies' reason for choosing the statutory scheme was that a lower level of reporting was required.
- Data quality would need to be audited by a third party and some companies have inter-company sales for which it would be difficult to provide data.
- The data is not always in a format that is simple to prepare for a return.
- The 2013 Regulations already require companies to provide information on sales income received from each presentation.

Government response

2.38. The Department would like to clarify its intention regarding these proposals. The proposed new information requirements are to help the Department to be able to enforce the existing controls over maximum price. It will strengthen our ability to verify whether a breach has definitely occurred (if this was in doubt) or if a breach has occurred to calculate the recoverable sum. For this purpose the information needed is the actual amount charged for specified presentation(s) and for specified time period(s).

2.39. The definition of the recoverable sum is set out in the Schedule to the 2008 Regulations. The basic calculation for the recoverable sum is:

"the difference between the amount which a person would have received had the product been supplied at the maximum price and the amount that the person actually received."

2.40. The new information requirements will assist the Department in determining the recoverable sum, and in particular 'the amount that the person actually received' for a particular presentation, if it needs to do so. This amount will be compared to 'the price at which that presentation was on sale for health service purposes on 1st December 2013 less 15 per cent', which cannot be higher than the price originally agreed by the Secretary of State through the Department of Health, adjusted to take account of the price adjustments applied to that presentation either by way of regulations and/or as a result of the manufacturer or supplier's previous membership of the voluntary scheme.

2.41. The proposed new information requirements are different from the requirements for information on average selling prices and are for a different purpose. As some respondents have correctly commented, and as we have noted in the consultation document, the 2013 Regulations already require manufacturers and suppliers to submit information regarding the total sales income and total number of presentations supplied in respect of each presentation over the period of time specified in the regulations, i.e. for two specified periods in 2014 and annually from 2015 onwards. Those Regulations enable the Department to gather information on average selling prices in order to establish reference period data in preparation for possible changes in later amendment regulations regarding price adjustments on average selling prices. We made clear in the current consultation that we are not proposing to introduce controls on average selling price at this time.

2.42. Information on average selling price could not allow the Department to verify that a breach of the price limit had definitely occurred (if this was in doubt) or, if a breach had occurred, to calculate the recoverable sum.

2.43. The Department acknowledges respondents' concerns regarding the potential impact of new information requirements on smaller companies. It is not our intention to require the information to be supplied regularly – we would only need to request the information from a company in the very rare case where the Department reasonably believes that a breach in the regulation on maximum price has occurred. Provided that a company complies with the Regulations and does not breach the limit on price then it would not expect to receive such a request. We believe that it is in all companies' interests that the regulations can be enforced in a fair and consistent way.

2.44. The Department can also provide reassurance that the only information required would be the amount the company itself received and would not, for example, require a manufacturer to obtain information on wholesaler margins. Any enforcement action would only be brought against the company that has themselves breached the regulations.

2.45. With regard to comments on administrative burden, we have stated that we expect that companies are already required to keep information on sales transactions in their accounts and the majority of industry respondents confirmed in their submissions that they did. Furthermore, and in line with standard accounting requirements, we would only require companies to keep the information for a maximum of six years. It is our intention to give companies a minimum of 28 days to respond to any request for this information. We do not propose to require the information to be independently audited, though of course we would expect any company concerned to provide accurate and complete information as required. We have noted the suggestion made by a number of respondents on developing a standard format for submitting the information.

2.46. We believe that the above clarification addresses the concerns raised by respondents. Our aim is to improve the Department's ability to apply the limit on maximum price in a fair and consistent way. We have therefore decided to amend the 2007 Regulations as proposed to introduce the new information requirements.

2.47. The current exemption from the information requirements for manufacturers and suppliers with sales income of less than £5 million for branded health service medicines will continue to apply to these new information requirements.

2.48. The existing schedule of penalties in the 2007 Regulations for not complying with the information requirements will apply to these new information requirements. These would enable the Department to take action against a company if it failed to comply with a reasonable request to supply this information.

Other Comments

Question 7: We asked, "Do you have any other comments about the consultation proposals"?

2.49. In addition to comments received on the price adjustment proposal, a small number of industry respondents raised the availability to companies covered by the statutory scheme of the option to make a proposal for a Patient Access Scheme in the context of a NICE technology appraisal.

Government response

2.50. The PAS provisions form part of the 2014 PPRS, and the option to propose a PAS for a relevant product is open to any company that is a member of, or which decides to join, the PPRS. It is important to note that there are no equivalent provisions in the statutory scheme.

2.51. While the PPRS and the statutory scheme share some overarching objectives around safeguarding the financial position of the NHS, there are a number of significant differences between the two schemes. As a general point, the inclusion of any particular provisions or mechanisms within the PPRS cannot be taken to

imply that it would be feasible or appropriate to apply similar arrangements in relation to a company that has not chosen to become a member of the PPRS. Notwithstanding this, the Department notes the points raised in consultation responses in relation to the availability of the option to propose a PAS, and we are undertaking further work to fully consider these issues.

Over the counter (OTC) Medicines

2.52. As stated in the consultation document and in our previously published statement[10], we are amending the regulations to make clear that the limit on price only applies to prescription only medicines supplied to the health service. In particular the definition of 'presentation' in the 2007 and 2008 Regulations will be amended so that the limit on price and the information requirements only apply to relevant medicines. The amendments clarify that a "relevant medicine" for the purposes of applying controls on prices under regulations 2 and 3 of the 2008 Regulations, means a medicine which is both a prescription only medicine and a branded health service medicine.

2.53. The reference to "branded health service medicines for health service use in the United Kingdom" in regulation 3 of the 2007 Regulations and regulation 2 of the 2008 Regulations (for the purposes of defining smaller companies that are exempted entirely from the regulations) remains unchanged and is in line with the exemption from PPRS Payments in the voluntary scheme. The definition of "branded health service medicines" covers all branded health service medicines and includes Pharmacy (P), General Sales List (GSL) and Prescription Only Medicine (POM) presentations. If a company's sales of branded health service medicines, including these products, is above £5 million, then the limit on the maximum price will only apply to "relevant medicines".

Clarification of the effect of procurement law

2.54. The consultation document mentioned that an issue had been raised about the application of the regulations to certain framework agreements tendered under European and UK procurement law and that we intended to clarify the regulations in this regard. We did not seek views on this issue as it is a matter of clarifying the application of existing law.

2.55. Subsequently the Department published a statement on the Gov.UK website on 6 November 2014 to clarify the application of the 2013 Regulations in this regard (at https://www.gov.uk/government/news/price-of-branded-medicines-clarification-of-regulations) The statement made clear that the price cut in the 2013 regulations does not apply to any presentation:

10 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/312120/OTCM_Statement_2014.pdf

- which is procured under one or more framework agreements under the Public Contracts Regulations 2006 (as amended) that were entered into on or before 31 December 2013 and/or that were entered into following a tender which closed on or before 31 December 2013;
- where the price specified under such framework agreement is more than the price at which that presentation was on sale for health service purposes on 1 December 2013 less 15% (without regard to any discount or other variation of the price which did not have general application on that date).

The effect of this interpretation is specifically limited to transactions called off such frameworks and only until the end of the relevant framework agreement. We have made amendments to the 2008 Regulations in respect of the price cut made under the 2013 Regulations to clarify the application of the law as set out in the statement.

Chapter 3 Next steps

3.1 Regulations which amend the Statutory Scheme (as set out in the 2007 Regulations and 2008 Regulations) will be laid before Parliament in February and will come into force following the normal 28 days for Parliamentary scrutiny. In addition to the changes outlined in this document, there will also be some small amendments to the 2007 Regulations and 2008 Regulations for clarity and consistency but these will not change the substance of the Regulations.

Annex A - List of respondents to the consultation

No	Organisation
1	Galen Limited
2	Ethical Medicines Industry Group
3	RFW Associates
4	Mallinckrodt Pharmaceuticals
5	UK Primary Immune-deficiency Patient Support
6	Teva UK
7	MAP Bio Pharma Ltd
8	Consilient Health Ltd
9	ABPI
10	Sandoz Limited
11	CSL Behring
12	NHS England
13	Grifols UK Ltd
14	HRA Pharma UK and Ireland Ltd
15	Merck Serono Ltd
16	Roche Products Ltd
17	Vifor Pharma UK Ltd
18	Individual Response
19	AstraZeneca
20	British Generic Manufacturers Association
21	Barking & Dagenham, Havering & Redbridge CCGs
22	Cancer Research UK
23	Dispensing Doctors' Association
24	Pharmaceutical Services Negotiating Committee
25	Bracco UK Ltd
26	ViiV Healthcare

27	GSK
28	Gilead
29	CSU Lead pharmacist prescribing advisor