



Department
of Health

Government Response to the Consultation on Revisions to the Statutory Scheme to Control the Prices of Branded NHS Medicines

November 2013

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Government Response to the Consultation on Revisions to the Statutory Scheme to Control the Prices of Branded NHS Medicines

Prepared by the Department of Health

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Chapter 1 - Introduction

1. The National Health Service (NHS) spends about £12 billion a year on branded prescription medicines in the UK. The Pharmaceutical Price Regulation Scheme (PPRS) is the main mechanism which the Department of Health (on behalf of the UK Health Departments) uses to control the prices of these branded medicines, by regulating the profits that companies can make on their sales. It is a voluntary agreement made between the Department of Health and the branded pharmaceutical industry, which is represented by the Association of the British Pharmaceutical Industry (ABPI). It has existed in various forms in the UK for over 50 years but has been renegotiated approximately every five years. The terms of the scheme have changed over time to reflect developments in the NHS and the pharmaceutical industry.
2. In August 2012 the Government confirmed its intention to negotiate new arrangements for the pricing of branded medicines to replace the current PPRS. The current PPRS will terminate on 31 December 2013 and the Government's intention is that a new agreement will come into effect in January 2014. Alongside new voluntary arrangements, the Government has planned to implement revisions to the statutory scheme that would apply to any company which chooses not to join the voluntary scheme.
3. The Government and industry have set out the key parameters for the next voluntary agreement in a set of Heads of Agreement, published in parallel to this document. Details of the Heads of Agreement can be found at www.gov.uk.

The Consultation

4. On 20 June 2013, the Government published the *Consultation on Revisions to the Statutory Scheme to Control the Prices of Branded NHS Medicines*.
5. The Government's intention was to strengthen the statutory scheme, removing certain exemptions and aligning it more closely to the core elements in the voluntary PPRS agreement. We proposed several key changes to the statutory scheme to reflect the above. These included:
 - Establishing revised reference prices;
 - Introducing a new price adjustment;
 - Removing the exemption to the price adjustment established by the £450,000 low cost presentation provision;
 - Introducing a small firms exemption covering those with total UK sales of branded medicines to the NHS of less than £5 million;
 - Introducing price controls on average selling prices (ASPs) within hospitals; and
 - Making specific provisions for the pricing of line extensions.

Responses

6. We are grateful to all those who responded to the consultation.
7. A total of 79 responses were received, 62 of these were from pharmaceutical companies and their representative bodies. The remainder were from pharmacy trade bodies, NHS and other organisations, a charity organisation and an individual response. Annex A lists the respondents.

This Report

8. This report summarises the main themes in the written responses to the consultation, and the Government's responses to these.
9. The complex nature of some of the proposals, specifically around ASPs and line extensions, and the broad range of views expressed in responses on these issues, has convinced us of the need to give these areas further consideration.
10. The key themes emerging from the consultation responses were:
 - Objections mainly by pharmaceutical companies to the suggested levels of the downward price adjustment;
 - Some concern, mainly from pharmaceutical companies, about the proposal to apply the price adjustment to ASPs to medicines purchased by hospitals;
 - Some support for retention of the £450,000 low cost presentation provision;
 - Many objections to the proposed removal of the £25m threshold for the information provision exemption. There was support for the proposed small firms exemption, but a number thought that the £5m threshold was too low and should be increased; and
 - Some perceived the information requirement as a result of proposals in the consultation to be unnecessarily burdensome.

Chapter 2 - Summary of key responses to the consultation questions and the Government's response to them

Price Adjustment

Question 1: We asked, “Views are invited on the suggested levels of the price adjustment. Should this be the same as that agreed as part of the PPRS negotiations?”

11. More than a third of respondents, mainly from pharmaceutical companies and their representative bodies, commented on this question. The majority (including all those from industry stakeholders) expressed a view that there was no justification for any level of price cut, stating that prices of UK branded medicines continue to be among the lowest in Europe. Furthermore, there were arguments that the level of price adjustment proposed could have detrimental consequences such as exacerbating shortages of medicines caused by unpredictable parallel trade, and an adverse impact on patient access to some medicines.

Government's response

12. While we consulted on a range of potential price cuts, we indicated in the consultation that we would take account of the negotiations in the voluntary scheme.

13. The Government has decided that taking into account all the issues including the state of public finances and the content of the Heads of Agreement for the PPRS published on 6 November 2013 that prices in the statutory scheme should be cut. It has decided it would be appropriate to cut prices by 15% from 1 January 2014.

14. The Government has noted the comments about international price comparisons. As stated in the eleventh Report to Parliament on the PPRS¹, international price comparisons for medicines need to be interpreted with some caution, particularly when they are used to compare prices over time. For example these comparisons do not take account of discounts. The issues about risks to supply are addressed in the Government's response to Question 3.

¹ Pharmaceutical Price Regulation Scheme: 11th Report to Parliament, DH, February 2012
www.gov.uk/government/publications/pharmaceutical-price-regulation-scheme-11th-report-to-parliament

Low Cost Presentations

Question 2: We asked, “Do you think it is right that the £450,000 low cost presentation should be removed?”

15. About half the respondents, mainly from industry, were against the removal of this threshold. They argued that it could affect the commercial viability of low revenue medicines. Others did not respond or offered no comments. A few of the respondents thought the threshold should be increased.

Question 3: We asked, “Are there any possible unintended or detrimental consequences which need to be mitigated against?”

16. Not many respondents commented on this question, but those who did, mainly from industry, broadly mentioned withdrawal of much needed niche medicines from the UK market and potential administrative burdens as possible consequences.

Government’s response

17. We remain of the view that the £450,000 low cost presentation exemption needs to be removed so that it no longer provides a de facto exemption for those drugs which are sold mostly into secondary care.

18. We are committed to ensuring the continuity of supply of medicines, including niche medicines and so have retained provisions in the statutory scheme to support this. In the event that the price adjustment, or other factors, renders a drug uneconomic to produce, a company can apply to the Secretary of State for a price increase (the process for which is set out in The Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008). The Secretary of State may also decide to exempt a drug from the price controls to ensure continuity of supply.

19. We believe these measures provide sufficient flexibility in the system to address the potential concerns raised, and consequently will remove the £450,000 low cost presentation as planned.

Small Firms Exemption

Question 4: We asked, “Do you agree that the £25 million information exemption should be removed?”

20. Most of the respondents, made up of pharmaceutical companies and their representative bodies, did not support the proposed removal of the £25m threshold as they thought that it would place a significant additional administrative and cost burden on smaller companies. Some argued that such a change would be perceived as running contrary to other

Government commitments such as the Red Tape challenge² and the *Strategy for UK Life Sciences*³.

21. Some respondents, mainly from other organisations, agreed this exemption could be removed, so long as other exemptions are considered to avoid an excessive burden on small firms.

Government's response

22. We acknowledge the concerns that have been raised about the proposed removal of the £25 million information exemption. However, it should be noted that companies in the PPRS supply this data as a matter of course, and it is our view that the likely administrative cost burden is proportionate. We are cognisant of the need to ensure that small firms are not unduly affected by these requirements. To support the Government's wider Better Regulation agenda to ensure that small and medium sized companies will be protected from additional burdens, we have therefore proposed the £5 million small firms exemption (see questions 5 and 6). We note the concerns raised about the alignment between the proposed change and the life sciences strategy agenda. However, we feel that the exemption for small firms takes account of the changing nature of the health life sciences sector, with the growing importance of small firms' role in driving both innovation and, potentially, growth. We believe it to be consistent with our commitment to making the UK a world-leading place for life sciences investment through the *Strategy for UK Life Sciences*.

Question 5: We asked, "Is the proposed £5 million small firms exemption needed?"

23. Few respondents commented on this question, but those who did agreed with the small firms exemption to the information provisions and the price adjustment, as they thought it could stimulate innovation and attract academic interest and investment. Some took the view that the threshold should be higher.

Question 6: We asked, "Is the proposed small firms exemption set at the right level? Will companies be able to evidence that they are under this level without difficulty, either through audited company accounts, or documenting a quality assurance process?"

24. Some respondents from the pharmaceutical industry commented on this question. A number highlighted the EU definition of small companies with sales of less than Euros 10 million, i.e. about £8-9 million.
25. Among those who responded to this question, there were mixed views on whether audited company accounts would provide sufficient evidence to ascertain whether a company was below the exemption level.

² www.redtapechallenge.cabinetoffice.gov.uk/home/index/

³ Strategy for UK life sciences, Department for Business, Innovation & Skills and Office for Life Sciences, December 2011, www.gov.uk/government/publications/uk-life-sciences-strategy

Government's response

26. The responses, though few, were supportive of the introduction of an exemption for small firms covering the price adjustment and information provisions. We acknowledge the points made about the level of the exemption, which some stated should be higher. However, we have decided to introduce the small firms exemption at the proposed level, namely for all companies with UK sales of branded health service medicines of less than £5 million in the relevant calendar year. This aligns it to the small firms exemption set out in the Heads of Agreement on a new voluntary pricing arrangement which will come into effect on 1 January 2014.
27. We have considered the points made about the information to be used to evidence eligibility for the exemption, and noted concerns from some quarters about the use of audited accounts. However, our experience with the voluntary scheme suggests that, even where statutory accounts do not hold the necessary information, companies will be able to provide this without too much difficulty.

Average Selling Prices (ASPs)

Question 7: We asked, "Do you agree with the proposal to apply the price adjustment to ASPs in hospital, aligning this more closely with the PPRS?"

28. Just over a third of respondents, most from industry, commented on this question, with the majority of these objecting to this proposal. Many suggested it would be difficult to ascertain an accurate ASP. Other arguments were that it wasn't appropriate to apply price cuts on top of existing discounts, and there were concerns about how this would fit with current tendering arrangements. More particularly, some expressed a view that products with a Patient Access Scheme (PAS) should be exempt from any price adjustment to ASPs in hospitals as they suggested that PAS already deliver significant savings to the NHS. Some thought that the proposal might have unintended consequences such as disruption of supply, and impact on global reference pricing.
29. A small number of responses, mainly from organisations other than pharmaceutical manufacturers, supported the proposal, or acknowledged that it could have positive benefits.

Question 8: We asked, "Does the suggested calculation accurately capture ASPs?"

30. Many did not respond to this question. Of those who did, some asked why, for 2015 onwards, the calculation would be drawn from a different period (i.e. 1 October 2013 to 30 September 2014). There were concerns that this would lead to incorrect calculations as this revised period is inclusive of months in 2014 when the new scheme would already be effective.
31. Doubts were also raised that data drawn from only 1 October 2013 to 30 November 2013 would be sufficient to give an accurate representation of ASPs.

Government's response

32. We realise that this is a complex issue and acknowledge the concerns raised. Consequently, we will be giving this further consideration and will not be introducing price adjustments on ASPs as part of these regulations.

33. In relation to PAS, these are schemes proposed by a pharmaceutical company in the context of a NICE technology appraisal with the purpose of improving the cost-effectiveness of a drug. PAS have proven a useful tool within the 2009 PPRS in facilitating patient access to some medicines that might not otherwise have been recommended by NICE.

34. However, even taking account of a PAS, many of these products remain at the upper limit of what the NHS can routinely afford to fund. Importantly, the health benefits NHS patients receive from these drugs are offset by other NHS patients' losses in health as funding is switched from other treatments. This means that, in general, medicines with a PAS do not offer significant net health gains to patients across the NHS as a whole. In view of this, the Government considers that it is appropriate and fair to apply price adjustments equally to drugs with a PAS as to any other branded medicine. We are not persuaded that there is a case to exempt drugs with a PAS from any future measures to introduce price controls on ASPs in secondary care.

Question 9: We asked, "Are the suggested changes to the information requirements right, or would other information be needed?"

35. Less than half of the respondents commented on this question. Those who did were mainly from industry and said that the requirement to provide audited information within 28 days would be very challenging, could be unrealistic for small firms and could disproportionately increase administrative burdens and external auditing costs. They also highlighted the need to clarify treatment for products not supplied during these periods e.g. seasonal products.

36. Responses also highlighted that the year ends of most companies for accounting purposes do not coincide with 30 September, and information would have to be captured quarterly to fit the proposed reporting period.

Question 10: We asked, "Do you agree that the proposed changes to ensure quality assurance of information are right? How might this best be put into practice?"

37. Less than a quarter of respondents commented on this question - most did not agree with the proposed changes. Concerns were also expressed on the likely administrative burden which would be associated with the proposed changes.

Government's response

38. We acknowledge the concerns raised about the 28 day period for provision of information, and accept that companies could find this challenging. Consequently, we have changed the requirement so that companies will have 2 months to provide the required information.

39. We recognise that some respondents have concerns about the proposed changes around quality assurance of information. However, it is clearly important that some form of assurance is provided, and we believe that the proposals are proportionate, with a requirement to provide audited information only if available, or alternatively to identify how data has been quality assured. It is our view that this would have only a small impact on the existing administrative burden.
40. We will also be making some changes to the data collection periods. As previously mentioned, we are giving further consideration to how we could introduce ASPs in the statutory scheme. We will therefore still need relevant reference period data. However, reflecting concerns that the previous period of 1 October to 30 November 2013 was too short to be representative, we have decided to change the data collection periods to 1 January to 31 August 2014.
41. It has always been the case that companies have been required to provide information to a set schedule, which was not aligned to their year ends. The proposed changes do not, therefore, impose any significant change in this respect.

Line Extensions

Question 11: We asked, “Do you agree that it is reasonable to incorporate line extensions?”

42. A few respondents, mainly from industry and their representative bodies, commented on this question. They said that the principle of determining the price of line extensions based on existing presentations is reasonable in cases where a simple change has been made, such as change of pack size or excipients. However, some responses argued that different considerations would need to be applied in the case of major new line extensions which result from additional development investment. Some thought that it would be reasonable to apply pro rata calculations for larger pack sizes.

Question 12: We asked, “Do you have any suggestion about how pricing decisions for line extensions should be made?”

43. The majority of respondents did not respond to this question.
44. Some respondents from the industry suggested that a pro rata pricing mechanism would be appropriate and welcome for simple line extensions, but suggested that an alternative proposal would be required for more complex line extensions, which could, for example, take account of factors such as the cost of development and patient benefit.
45. Others thought that a line extension should be treated as a new product with freedom of pricing, provided it has been developed with a large level of company investment and offered significant value to patients and the health and social care system. However they

did not suggest what would represent a large level of investment and/or significant patient value, nor how companies would demonstrate this.

Government's response

46. As with the introduction of ASPs, this is a complex issue which requires further consideration. Consequently, we will not be introducing specific provisions on line extensions at this time.

Penalties

Question 13: We asked, "Do you agree that the penalties schedule should refer to total UK sales as determined by a company's audited accounts instead of health service sales as determined by an Annual Financial Return?"

47. Few respondents commented on this question. Some did not agree that the penalties schedule should be determined by total sales as determined by audited accounts. Some thought that this would create an uneven playing field, given that a company's UK sales will include sales not made to the health service. They would prefer penalties to relate only to NHS sales of branded products and exclude sales to private hospitals or other manufacturers.

Government's response

48. We recognise that some respondents have expressed concerns about this proposed change, and we will therefore continue to base the penalties on UK health service sales. However, if a company has not provided the necessary information to determine the penalty charge level, we will apply the higher penalty level until information is provided to determine otherwise.

Impact Assessment

Question 14: We asked, "Do you agree with the assumptions and analysis on the costs and benefits of the proposed changes?"

49. More than a third of respondents from the industry, their representative bodies, the NHS and other organisations commented on this question. Some of the assumptions and analysis in the Impact Assessment were challenged.

50. Particular comments were made on: the impact of price reductions on R&D investment in the UK; impacts through international reference pricing; and impacts on supply of medicines. There were also technical comments about the analysis in the Impact Assessment, in particular the treatment of impacts on profits to overseas shareholders.

Government's response

51. The Government still considers that the assumptions and analysis in the Impact Assessment are appropriate.

52. In particular: the Government believes there is no reason to expect that changes in UK prices would significantly affect the UK's attractiveness as a location for R&D, which depends on the suitability of the UK for conducting R&D and is determined mainly by factors such as the fiscal environment and the availability of scientific expertise; while there may be an indirect effect on company profits through international reference pricing, this is expected to be highly diluted and not ultimately significant; and, the vast majority of branded pharmaceuticals are sold at a price which greatly exceeds their costs of supply, so it is unlikely that any price cut under consideration would affect companies' ability to supply medicines. The analytical approach used in the Impact Assessment is consistent with the methodology specified in the *Green Book*⁴.

53. The final version of the Impact Assessment includes a more detailed account of the comments made, and the Government's detailed response and justification of its approach.

Question 15: We asked, "Do you agree that there will be no specific impact from the proposed changes on any particular groups, specifically those covered by the Public Sector Equality Duty?"

54. Less than a quarter of respondents commented on this question. There were no specific comments on potential impacts for particular groups or on the Public Sector Equality Duty⁵. The responses instead reiterated earlier points, e.g. suggestions that the proposed changes could adversely impact on patient access to niche medicines as some long established medicines may well become uneconomic to supply and may be withdrawn.

Government's response

55. Promoting equality is a key priority for the Government. We note that consultation respondents did not identify any potential specific impacts of our proposals on particular groups covered by the Public Sector Equality Duty. Nevertheless, we will keep this issue under review as our work progresses, and, should any potential disproportionate impacts on particular groups be identified, we will consider the potential for mitigating actions. More generally, it remains our objective to deliver the best possible outcomes for all NHS patients, regardless of their personal characteristics. We believe that the steps we are taking to strengthen the statutory pricing scheme for branded medicines, alongside the negotiations on new voluntary arrangements, will play an important part in ensuring patient access to innovative and effective medicines, at prices that represent value to the NHS.

⁴ The Green Book, HM Treasury, July 2011, <https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-government>,

⁵ Public Sector Equality Duty, April 2011, <http://www.legislation.gov.uk/ukpga/2010/15/section/149>

Question 16: We asked, “Is it likely that the proposed changes will create any risks around continuity of supply of branded medicines?”

56. Less than a quarter of respondents commented on this question. Those who did were mainly from the pharmaceutical industry and thought the proposed changes could have significant impacts on the supply of branded medicines which could pose a major risk to patient health and wellbeing.

Government’s response

57. We have taken on board the concerns raised by respondents about the possible impact of the proposed changes on the continuity of supply of medicines. We recognise the complexity of making changes in some areas, such as ASPs and line extensions, and have committed to giving this further consideration. There were also some specific concerns around supply of niche medicines in relation to the £450,000 low cost presentation exemption. As we noted in the response to questions 2 and 3, there are mechanisms already in place within the current regulatory provisions which provide a means to address these issues. A company can, for example, apply for a price increase, or the Secretary of State can, instead, make the decision to exempt a particular presentation from the price controls for a given period to ensure continuity of supply.

Chapter 3 - Next steps

58. The revised statutory scheme Regulations, which take account of the changes outlined in this document, will be laid before Parliament in November and will come into force on 1 January 2014.
59. Further consideration will be given to feedback on the introduction of price adjustments on ASPs and line extensions, and the intention is that a further consultation response document will follow in 2014.

Annex A

List of respondents to the consultation

1. Alliance Boots
2. Merz Pharma
3. Almirral
4. Otsuka
5. BioMarin
6. Forest Laboratories
7. Napp Pharmaceuticals
8. Shire
9. Galderma UK
10. Internis Pharmaceuticals
11. Dermal Laboratories
12. Vifor Pharma
13. Eisai
14. Flynn Pharma
15. Grunenthal
16. Lundbeck
17. Teva UK
18. Bristol-Myers Squibb
19. MEDA Pharma
20. MEDA UK
21. ProStrakan
22. Janssen-Cilag
23. Norgine Pharmaceuticals
24. Amgen
25. Genus Pharmaceuticals
26. Celgene
27. The Medicines Company
28. Daiichi Sankyo UK
29. Pfizer
30. Roche
31. ALK
32. Archimedes Pharma
33. Fresenius Kabi
34. Astra Zeneca
35. Merck Sharp & Dohme
36. Lilly UK
37. Merck Serono
38. Genzyme
39. Sanofi

40. Novo Nordisk
41. MEDA Pharmaceuticals
42. Gilead
43. CSL Behring
44. Spectrum Thea Pharmaceuticals
45. Novartis Consumer Health
46. Novartis Pharmaceuticals
47. Boehringer Ingelheim
48. Leo Pharma
49. Speciality European Pharma
50. UCB Pharma
51. Baxter Healthcare
52. Wockhardt
53. Johnson & Johnson
54. Ipsen
55. InterMune
56. Alcon
57. Alliance Pharma
58. GSK
59. Sandoz
60. Abbvie
61. HRA Pharma
62. Morningside Healthcare
63. Association for the British Pharmaceutical Industry
64. BIA
65. British Generic Manufacturers Association
66. American Pharmaceuticals Group
67. European Medicines Group
68. Ethical Medicines Group
69. British Association of Pharmaceutical Wholesalers
70. Guild of Healthcare Pharmacists
71. Pharmaceutical Services Negotiating Committee
72. NHS Dorset Clinical Commissioning Group
73. Community Pharmacy Scotland
74. NHS National Services Scotland
75. Cancer Research UK
76. Management Clinical Lead and GP – NHS Gloucestershire CCG
77. Chairs of Pharmacy Market Support Group and National Pharmacy Support Group
78. RFW Associates
79. Individual response