Department of Health

Changes to the statutory scheme to control the prices of branded health service medicines

Consultation response

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Prepared by Department of Health; Medicines and Pharmacy Directorate

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Introduction

1. The Government consulted on changes to the statutory scheme to control the cost of branded health service medicines. The consultation closed on 4th December 2015. The proposals subject to the consultation sought to better align the way the statutory scheme and voluntary 2014 Pharmaceutical Price Regulation Scheme work, to move towards a more level playing field between companies in the two schemes. Reforming the statutory scheme would also enable the Department to put more effective price and enforcement controls in place, whilst increasing the levels of savings of health service medicines covered by the scheme.
2. Fifty one formal responses were received from a variety of organisations including the pharmaceutical industry, patient groups, NHS organisations and charities. In addition to the formal consultation, the Department undertook round-table discussions with the relevant stakeholders to discuss the challenges the Department is addressing and potential solutions.
3. The Government recognises that it is important we get these changes right for patients, the NHS and industry. We looked in particular at minimising the impact on small and medium sized businesses, while securing the medicines patients need at a cost which the NHS can afford.
4. This consultation response provides a summary of the key issues identified throughout the consultation process and provides the Department's response to those issues.

Alignment of statutory scheme savings with PPRS

5. The consultation set out four potential options to better align the savings from the statutory and voluntary schemes (relative to the total sales covered by each scheme). In summary these options were:
    - Option 1: A price cut (of between 20% and 30%) in the maximum price of presentations on sale for health service purposes on 1st December 2013.
    - Option 1a: As option 1, and also a price cut (of between 20% and 30%) in the maximum price on 1st September 2015 of presentations introduced for sale for health service purposes after 1st December 2013.
    - 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 deducting VAT and discounts. The level of payment percentage proposed was between 10 -17%.
    - Option 2a: As with 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. The level of payment percentage proposed was between 10-17%.

6. The consultation stated the Department's preferred option was option 2a (introducing a payment mechanism applicable to new as well as old products).

Responses to the consultation

7. The remainder of the document goes through each of the consultation questions summarising the responses to the consultation and then setting out the Government's response.

Question 1: The consultation sought views on the factors which should be taken into account and to what extent further limits on the cost of branded health service medicines should be applied.

Question 2: The consultation also sought views on the potential price adjustments and payment percentages, or potential alternatives, subject to the consultation.

8. NHS organisations, patient and other representative groups generally supported the Government's preferred option as a mechanism to remove disparities between the PPRS and the statutory scheme. The organisations within this group also largely considered that this option would be equitable to all suppliers and would maximise savings. NHS England asked the Government to consider maintaining current 15% price cut as well as implementing a payment percentage due to a risk of companies increasing existing prices (incurring higher costs).
9. Responses from the pharmaceutical industry largely disagreed with the proposals to implement either a price adjustment or a payment mechanism. The concerns broadly fell into the following themes:

    Market sentiment: That changes proposed could be viewed by global pharmaceutical boards as creating an unsettled market.

    Voluntary and statutory scheme offer: The two schemes should remain distinct from one another and that the risks of companies switching are unrelated to the level of savings generated under the statutory scheme. However, some companies agreed with the Government that there should be no commercial difference between each scheme.

    Legislative powers: The majority of industry responses suggested the Government does not have sufficient legal basis in domestic legislation to implement its preferred option, with some responses also suggesting the proposal amounted to a 'sales tax'. Some responses also suggested that the proposals were in conflict with European legislation, including the Transparency Directive.[1]

    Treatment of tenders/procurement frameworks: Industry responses in general proposed that products provided under tenders and procurement frameworks should be exempt.

[1] Directive 89/105/EC (relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health care systems).

Exemption of specific products: Some industry and patient groups argued for exclusions for specific products, for example plasma protein products, on the basis of having a unique cost structure, supply channels or demand management programmes.

Supply: Industry responses suggested that proposals could lead to potential supply issues and the withdrawal of products from the UK market.

Impact Assessment: Responses from pharmaceutical organisations challenged the assumptions and estimated savings provided in the impact assessment.

Government response

General

10. The purpose of the statutory scheme is to safeguard the financial position of the NHS by ensuring there are similar limits as those provided in the PPRS to the cost of branded health service medicines supplied by companies that decide not to join the PPRS.

11. One of the aims and benefits of the voluntary scheme is to provide stability and predictability to the Government and pharmaceutical industry. However, if the statutory alternative offers a very different commercial proposition and makes significantly lower savings in relative terms, as is the case now, the result is that there is inequity between the financial impacts of the two schemes. This also means the NHS loses out on the level of savings anticipated in the PPRS agreement. Since the PPRS began, a total of £157m of sales have moved from the PPRS to the statutory scheme. The Impact Assessment section below references further evidence for loss of anticipated savings.

12. There were no suggestions on alternatives to the options proposed in the consultation that would broadly align the relative savings from the statutory scheme with the PPRS.

13. The Government's conclusion is that Option 2a continues to be the best option for the following key reasons:

    - It would deliver the largest savings for the NHS. Given the continued challenging NHS financial position it is essential to do what can be done to deliver the level of protection that was envisaged in the 2014 PPRS.
    - It would better align the way the two schemes work and move towards a more level playing field for companies in either scheme and discourage switching from the PPRS.

Legislative powers

14. Industry responses have queried whether the Government has sufficient power to introduce a statutory payment mechanism similar to that which forms part of the agreed 2014 PPRS and some have made clear that they would challenge this view in the courts. The Government has therefore concluded that amendments should be made to the primary legislation (the National Health Service Act 2006) to put beyond doubt that the Secretary of State has the power to require a payment mechanism in the statutory scheme to limit the cost of health service medicines.

15. Subject to the passage of the legislation through Parliament and Royal Assent, the Government intends to carry out a further consultation seeking views on the operation of the proposed payment mechanism, and level of payment percentage. We would therefore expect changes to the statutory scheme to commence at the earliest during the financial year 2017/18.

Small to medium sized companies

16. The Government fully recognises the need to balance the interests of the NHS and patients in having available medicines on reasonable terms, with the need to minimise the burdens on small and medium companies and to take account of the cost of research and development. As proposed in the 2015 consultation we are committed to retaining the exemption from any new payment mechanism for companies with sales of branded health service medicine below £5m in the previous calendar year.

17. After considering the consultation responses carefully, we propose to exclude all health service sales of over the counter (OTC) medicines from a future payment system and to exclude sales of OTC medicines from the calculation of the £5m branded health service sales to qualify for the smaller companies' exemption. For clarity, OTC medicines are those which can be supplied with or without a prescription (also referred to as Pharmacy and General Sale List or P & GSL medicines). The regulations would therefore only apply to prescription only medicines (also known as POMs). This will benefit small to medium companies in particular.

18. The Government recognises that administrative simplicity is valued by some companies in the statutory scheme. Therefore while aiming to align the statutory scheme better with the PPRS in terms of savings, the consultation proposed ways in which administrative complexity could be kept to a minimum. The proposal to exclude all sales of OTC medicines from the regulations will reduce administrative burdens still further and the Government will consider further suggestions for reducing administrative complexity when consulting on draft regulations to implement a statutory payments system.

Treatment of tenders

19. Responses argued for sales of products under frameworks to be excluded from the payment system. As originally proposed in the consultation document, payments would not apply to sales of products procured under extant framework agreements (i.e. framework agreements made under the Public Contracts Regulations 2006 (as amended) that were entered into on or before, or were entered into following a tender which closed on or before, the date of coming into force of the new regulations). However the Government is not proposing to make an exemption for sales under future framework agreements not extant when the regulations were brought into force. Companies would be able to take into account in their tenders any payment mechanism that already applied.

Exemption of specific products

20. The Government has listened to concerns about maintaining adequate supplies of essential medicines and specific supply issues for products such as plasma protein therapies and nuclear isotopes. The Government recognises the need for provisions to allow for either temporary or permanent increases in maximum price in order to address short term or long term supply problems and ensure continued adequate supply of essential medicines.

Supply

21. The Government considers that the ability to increase prices is the right way to address short or long term supply problems, where these circumstances are dependent on UK pricing. The consultation document made clear that with a payment system, it would be necessary to cap list prices (not allow them to increase) in order to avoid the savings being eroded by price increases. This is similar to the PPRS payment mechanism and means that the payment percentage acts in a similar way as a cut in average selling prices, delivering a real saving to the NHS, while being much simpler to administer. However if it became uneconomically viable to supply a particular medicine, companies could respond by increasing actual prices within the limit on maximum price or, if necessary, seeking temporary or permanent increases in the maximum price for supply reasons. We recognise that this would mean that in such cases the savings produced by the payment system would be offset by increases in price. However this should allow the market to determine the economically most efficient level of price increase (and reduction in savings to the NHS) necessary to secure adequate supply.

22. Consultation responses did not provide any explanation or evidence why companies would not be able to increase prices in this way if there was a supply problem which affected the market generally. In order to consider this issue further the Government would need to see what analysis and evidence underpins the argument that exemption from the payment percentage would be needed in addition to the provisions allowing price increases for supply reasons.

Impact Assessment

23. The Department has considered the responses, including commercially confidential information, in respect of the impact assessment and reviewed the methodology and data. We have concluded that the assumptions and estimated costs and benefits are a reasonable estimation of the impact of the options. The Government will publish an impact assessment alongside the proposed legislation which will include further analysis and evidence supporting the argument in favour of introducing a payment system into the statutory scheme. Subject to the passage of proposed legislation to clarify the Secretary of State's primary powers, the Government will also publish a further impact assessment alongside the consultation on the proposed regulations.

Question 3: Comments were also invited on how the proposal for a payment scheme might operate.

25. The responses highlighted a number of specific issues and concerns about how a payment scheme might operate in practice. These included:

    Data and estimates: Ensuring that the data underpinning the payment proposal provided sufficient certainty and reliability. Responses highlighted potential risks of relying on inaccurate estimates to calculate the payments. Responses also noted that wholesalers do not currently have reliable data sources to support a payment scheme.

    Reducing complexity: The 2014 PPRS payment scheme is complex and careful consideration is needed to ensure arrangements are equitable and manageable.

    Exemptions: Responses argued for specific groups of products to be exempt from the reforms to the statutory scheme. These included extant frameworks and central procurements, new products, products subject to brand equalisation and replicating the PPRS exemptions in the reforms to the statutory scheme. Specific concerns were raised about some products becoming commercially unviable.

Government response

26. The Government recognises the concerns from stakeholders about ensuring the data underpinning the changes to the statutory scheme are reliable. To minimise potential complexity, the Government proposed for the payment percentage to be set across the UK following consultation, and to be applied to new as well as older products, in order to align the savings from the voluntary and statutory schemes broadly (in relative terms). We consider this approach to be reasonable, minimising the need for complex estimations and readjustments associated with the PPRS payment mechanism.

27. The Government proposes to exclude companies with sales of health service prescription only medicines of under £5m a year, sales under procurement frameworks extant when the regulations come into force and all sales of OTC medicines. Subject to the passage of the legislation through Parliament and Royal Assent, the Government intends to carry out a further consultation seeking views on the operation of the proposed payment mechanism, and level of payment percentage, including whether there is a case for any further exemptions from the payment, which would of course reduce the savings for the NHS. As outlined above the Government considers that the ability to increase prices is the right way to address short or long term supply problems, allowing the market to determine the economically most efficient level of reduction in savings to the NHS necessary to secure adequate supply.

28. Many manufacturers supply to community pharmacists through wholesalers and may have to rely on data from third parties to estimate non-health services sales – for example private sales. As with the current PPRS, we propose to base payments on company sales data which is then independently audited to a standard specified in regulations and can be checked for accuracy against administrative data. This should result in estimates which are as accurate as they could reasonably be expected to be. This system has worked relatively smoothly for the PPRS.

29. The Government accepts, however, that it is not possible using current information systems to obtain a sufficiently accurate estimate of sales of OTC medicines under NHS prescriptions. So we propose to exclude OTC sales from proposals for a future payment mechanism. This does not affect the estimates of savings in the consultation impact assessment, as we did not have any information on NHS prescription sales of over the counter products.

Smaller companies

Question 4: The consultation sought views on proposals to maintain the current smaller company exemption threshold at below £5 million of branded health service medicines sales, and in line with the current PPRS.

30. Most industry responses agreed with this proposal. Responses also noted that sales should be monitored to know when the threshold is passed. A small number of responses argued that the threshold should be increased to levels between £10 million and £75 million. One response argued for a taper to be applied up to £50m.

Government response

31. Maintaining the exemption for smaller companies with sales of branded health service medicines below £5 million in the previous calendar year would align with the exemption in the current PPRS and align with the Government's policy of supporting small to medium enterprises. In view of the broad agreement in consultation responses the Government proposes to maintain this £5 million threshold. However, as set out above, the Government also proposes to exclude all sales of OTC medicines from the regulations and to exclude sales of OTC medicines from the calculation of the £5m branded health service sales to qualify for the smaller companies' exemption. The Government intends to carry out a further consultation seeking views on the operation of the proposed payment mechanism and will look at ways in which we can further minimise the burdens on small to medium sized companies.

Complexity

Question 5: Views were sought on proposals to keep administrative complexity to a minimum.

32. Responses agreed with the need to keep administrative burdens and complexity to a minimum. A small number of pharmaceutical companies suggested the payment mechanism would add a significant burden to their business when compared to a price cut in terms of staffing requirements to calculate payments for the end of quarters and potential work to account for adjustments.

Government response

33. The changes to the statutory scheme apply only to sales of branded health service medicines. Whilst the changes to the statutory scheme may result in some increase in administrative burden for some companies the Department believes it has proposed reasonable steps to ensure administrative complexities and burdens are proportionate whilst ensuring robust audit arrangements are in place. Subject to the passage of the legislation through Parliament and Royal Assent, the Government intends to carry out a further consultation seeking views on the operation of the proposed payment mechanism.

Price limits

Question 6: The Government sought views on specific proposals to

- **create and publish an archive list of maximum reference prices (covering the statutory and voluntary schemes)**
- **publish regular updates of current maximum prices on a separate list**
- **require companies to give at least 28 days' notice of the price of a product prior to launch**

34. Most responses generally agreed with the proposals and the principle of transparency. However some pharmaceutical industry responses questioned the value and benefit of publishing maximum prices. A concern was also raised about the practicalities of publishing company prices leading to potential confusion of different sources of price information and international reference pricing.

35. For products in multi-source markets, it was suggested the Department would need to respond rapidly within the 28 day notice period. It was also suggested that publication of prices should be accompanied with an explanation of the payment mechanism for both the voluntary and statutory scheme.

Government response

36. Subject to the passage of the legislation through Parliament and Royal Assent, the Government will reflect on the responses to this consultation and intends to carry out a further consultation seeking views on the operation of the proposed payment mechanism and amendments to provisions on price control, including time limits.

37. The Government considers that in the meantime there is still value in transparency terms in publishing an archive list of reference prices and periodically updated lists of current maximum price even in the absence of amendments to the regulations on price control. The Department is working with the NHS Business Services Authority to develop the proposed lists and intends to consult members of both the PPRS and the statutory scheme on the draft lists prior to publication in order to check accuracy.

Single source generics

Question 7: The Department sought views on whether to consider options available to limit prices of health service medicines for generic medicines where there is no competitive market to secure value for money.

39. Health system responses supported work to address the issue noting several instances where the price of a generic medicine has increased significantly. Industry responses challenged the basis for the Department's consideration of this issue largely grouped around three themes;

    - **Insufficient Consultation:** Some responses felt that there was insufficient consultation on this issue.
    - **Case for action:** Other responses stated the Competition and Markets Authority already had wide powers to regulate and deal with market abuses or the Department should seek further evidence, as in some instances price increases may not always be a signal of a less competitive market.
    - **Unintended consequences:** Some responses suggested that action in this area could lead to product withdrawal and supply shortages.

Government response

40. Officials of the Department of Health will continue to work closely with the Competition and Market Authority and alert them to any cases where the Department thinks there may be market abuse.

41. The Government will explore with the relevant stakeholders' representative bodies whether amendments are needed to the existing health service medicines supply pricing arrangements.

42. Subject to the passage of the legislation through Parliament and Royal Assent, the Government will amend legislation to enable it to take action on the price of generic medicines, should that be necessary.

43. The Government currently collects information about some generic medicines on a voluntary basis, such as through schemes M and Scheme W. However not all manufacturers, wholesalers and suppliers of generics participate in the schemes and therefore the information that is currently collected does not cover all sales of generic medicines. The Government therefore intends to legislate to require all parts of the supply chain to keep and supply, when the Secretary of State requests, information on sales and purchases of health service medicines. This information will enable more informed decisions on reimbursement and will help in evaluating the efficiency of the health service medicines supply pricing arrangements. The Government will consult further with stakeholders on the details of the information requirement policy and its implementation.

Temporary exemptions:

Question 8: The consultation sought views on the proposal to require a company to agree a temporary maximum price where a temporary exemption from price control is permitted and for the Secretary of State to set out the factors to take into account in making decisions on company requests for a permanent price increase and the information that can be reasonably requested to make the decision.

45. Most responses welcomed the flexibility of allowing temporary price increases in specific circumstances, such as in times of short term supply issues. Some responses highlighted concerns about the potential for there to be a large number of applications for temporary price increases.

46. Responses suggested a variety of factors that should be considered as part of the decision making for a permanent price increase, these included:

- a broad view of the clinical need of a medicine should be taken. Withdrawal of products could lead to the use of more expensive treatment options.
- Some products operate in markets which can change quickly.
- The maturity of products and increases in cost of goods could lead companies to divest products leading to discontinuation or price increases.
- Potential consequences of declining prices could lead to supply being diverted to other markets where the profit margin is higher.

Government response

47. Subject to the passage of the legislation through Parliament and Royal Assent, the Government intends to carry out a further consultation seeking views on the operation of the proposed payment mechanism system and amendments to provisions on price control.

48. As set out in the consultation, the Government proposes to allow for urgent, temporary exemptions from price controls to address imminent threats to continuity of supply. A provision of this nature is important in providing a flexible and rapid response to ensure continued adequate supply of essential medicines. However, as proposed in the 2015 consultation, companies will be required to agree the temporary maximum price with the Secretary of State.

49. As proposed, the Government will also allow for permanent increases in maximum prices for supply reasons. The Government will reflect on the responses to this consultation and will consult again on revised proposals on the factors that Secretary of State should take into account when making decisions on increases in maximum prices.

Penalties

Question 9: Views were sought on proposals to include provisions to allow the Secretary of State to apply the current levels of penalties in the 2007 regulations, including provisions to allow him to establish the level of penalties for the breaches by using a company's total UK sales, in cases where information on branded health service medicines is not available. In particular, the consultation sought views to apply penalties

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

51. Responses generally agreed that sanctions should apply that are effective and draw from the mechanisms in the 2007 regulations as proposed in the consultation. Some industry responses stated the approach was reasonable. Some responses from industry were concerned that the proposals for a payment mechanism would lead to a higher level of complexity and administrative burden and therefore that it was inevitable for mistakes to be made and that exceptions may need to be made in relation to applying the 28 days' notification period.

Government response

52. Subject to the passage of the legislation through Parliament and Royal Assent, the Government intends to carry out a further consultation seeking views on the operation of the proposed payment mechanism and amendments to provisions on price control. This will include proposals on the application and calculation of penalties required to ensure that the regulations are implemented effectively and fairly.

53. The Government welcomes the general support for the proposals on penalties in the 2015 consultation and would like to clarify that the Secretary of State would not be obliged to apply a penalty in the case of every breach. The Department will always try to work with companies to secure compliance without the necessity of charging penalties. Any company that is subject to enforcement action can appeal against the action. If the appeal is unsuccessful, or the company does not appeal, and in the case of continued non-compliance, then any debt owed to the Department by the company as a result of its non-compliance would be enforceable in court.

Public sector equalities duties and health inequalities

Question 10: The Department also sought comments, including evidence on how the proposals might affect groups protected by the public sector equalities duties and health inequalities.

55. Responses suggested that patients with specific conditions such as Immunodeficiency would be severely affected should these products be withdrawn from market, due to the cost structure, supply channels and demand management programmes. It was also suggested that elderly individuals, chronically ill or disabled individuals could be adversely impacted. However, responders did not provide further information or evidence.

Government response

56. We have considered the views and evidence put forward in the consultation response of how the proposals might affect groups protected by the public sector equalities duties and health inequalities duties. The Government's assessment continues to be that there is no detrimental impact on particular protected groups or on health inequalities. By generating greater savings for the NHS, the proposals should have a positive impact by increasing the resources available to provide treatments and services to patients across the NHS, including those with protected characteristics. The Government also recognises the necessity for provisions to allow for either temporary or permanent increases in maximum price in order to address short term or long term supply problems and ensure continued adequate supply of essential medicines.