Department of Health & Social Care

Proposed changes to the statutory scheme to control the costs of branded health service medicines

Consultation response

March 2020

Contents

Executive Summary

The statutory scheme acts alongside the 2019 Voluntary Scheme for Branded Medicines Pricing and Access (2019VS) to limit the growth in costs of branded health service medicines. This is done to safeguard the financial position of the NHS, while taking into account the need for medicinal products to be available for the health service on reasonable terms, the costs of research and development, and impacts on the UK life sciences industry, wider economy, and patients.

Companies that have opted not to join the current 2019VS, a non-contractual agreement, which replaced the previous Pharmaceutical Price Regulation Scheme (PPRS 2014) between the Government and industry, are members of the statutory scheme. The 2019VS began on 1 January 2019 and will run until the end of 2023.

Earlier this year, the Government consulted on changes to the current statutory scheme which operates under the Branded Health Service Medicines (Costs) Regulations 2018 ("the 2018 Regulations").

This document analyses the 63 responses received to that consultation and sets out the Government's intentions.

In summary, the Government will lower the payment percentages as currently set out in the 2018 Regulations. This would mean that from 1 April 2020, the payment percentage for 2020 will become 7.4%. However, to take into account where companies have made payments at 14.7% under the 2018 Regulations in the first three months of the year, these companies will have a reduced payment percentage of 5% for the rest of the year.

We also intend to amend the payment percentage for 2021 at the same time. This will apply for the whole of the year and to all statutory scheme companies. This will be changed to 10.9%.

Chapter 2 sets out the Government's consideration of responses received on the proposed changes to payment percentages to the statutory scheme for 2020 and 2021, whilst Chapter 3 covers responses received on the level of the amended payment percentages and the underlying methodology.

Following consideration of the responses made to the consultation, the Government has concluded that it is appropriate to reduce the payment percentage in 2020 from 14.7% to 7.4% and 10.9% for all scheme members in 2021. This is in line with the objective to maintain some broad commercial equivalence between the statutory and voluntary schemes.

Chapter 4, considers views expressed on our assessment of the impact of our proposals and the effect of those on those areas where the NHS Act 2006 requires we consider and consult. These include the economic consequences for the life sciences industry in the United Kingdom, the consequences for the economy of the United Kingdom, and the consequences for patients to whom any health service medicines are to be supplied and for other health service patients. Chapter 4 also includes industry views on our broader analysis of the impacts of the proposals. This analysis has now been updated with the latest available data on sales covered by extant frameworks. Furthermore, Government has determined that it is right to maintain a link between the statutory and voluntary schemes by using a consistent growth forecast across the two schemes.

Chapter 5 considers views expressed on our assessment of the implications on the statutory duties of the Secretary of State for Health.

Analysis of the relevant statutory duties in relation to the final decisions made about the proposed amendments are presented at Annex A, and the final impact assessment is published separately.

The amendments to the 2018 Regulations will be set out in Branded Health Service Medicines (Costs) (Amendment) Regulations 2020 ("the Amendment Regulations") and will come into force on 1 April 2020. A copy of the Amendment Regulations is published alongside this document. Operational guidance, produced by the Branded Medicines Operations team, was been published in draft following the coming into force of the 2018 Regulations, will be updated to support companies in the implementation of the changes to regulations.

We are required to also undertake an annual review of the legislation. We have completed this review in parallel to running this consultation exercise. This review considers the extent to which the 2018 Regulations have achieved their objectives, which are:

- To limit the growth in costs of branded health service medicines to safeguard the financial position of the NHS;

- To ensure medicines are available on reasonable terms, accounting for the costs of research and development; and

- To deliver the above objectives in a way consistent with supporting both the life sciences sector and broader economy.

This annual review is published alongside this document.

1. Introduction

1.1 The voluntary and the statutory schemes for pharmaceutical pricing limit the growth in costs of branded health service medicines. This is done to safeguard the financial position of the NHS, while taking into account the need for medicinal products to be available for the health service on reasonable terms, the costs of research and development, and impacts on the UK life sciences industry, wider economy, and patients. The statutory scheme is part of a broader set of measures, with which the Government seeks to create an environment where clinically and cost-effective medicines are supplied at an affordable cost, in a way consistent with supporting both the life sciences sector and the broader economy.

1.2 On 17 January 2020, the Government published a consultation on Proposed changes to the statutory scheme to control the costs of branded health service medicines. The purpose of the proposals, in line with commitments outlined in the annual review of the scheme in 2019, were to amend statutory scheme payment percentages for 2020 and 2021 to control growth at a rate of 1.1% per annum and to help ensure broad commercial equivalence with the 2019VS.

1.3 The consultation on these proposals closed on 18 February 2020, Overall, the Department of Health and Social Care (DHSC) received 63 responses to the consultation, of which 9 were from health service bodies and patient groups; 9 from pharmaceutical companies, trade bodies and industry consultants; and 45 from individual respondents. The rest of this document summarises the key issues raised in the responses to this consultation, and sets out the Government's response to those issues. It also includes an analysis of the impact of the proposed amendments on the Secretary of State's various statutory duties, such as the public sector equality duty and the Family Test.

2. Response on the Governments reason for proposed changes

2.1 Following consideration of the responses made to the consultation, the Government concludes that there should continue to be broad commercial equivalence between the statutory and voluntary schemes.

2.2 Each year the 2018 Regulations will be reviewed. If there is evidence that the payment percentages are no longer appropriate to deliver the objectives of the scheme, the Department will be able to consult on revisions to these payment percentages.

Question 1: Do you agree or disagree with the proposal to change the payment percentages? Please give reasons

Outline of consultation proposals

2.3 The consultation proposed to change the payment percentages for the statutory scheme for 2020 and 2021, to come into force from 1 April 2020.

2.4 The annual review mechanism allows us to consider whether the payment percentages remain reasonable. Based on the three-quarters of available data for 2019, the growth in those sales between 2018 and 2019 was lower than forecast, and therefore the payment percentages set for 2020 and 2021 were higher than required to control growth at 1.1% per annum.

2.5 Our intention is to ensure broad commercial equivalence between the statutory and voluntary schemes. This is to ensure companies are not making higher payments than required, and that payments made are reasonable and would not have potential, negative knock-on effects on supply and innovation in research and development. The current 2019VS payment percentage for 2020 is set at 5.9% to account for the lower than forecast growth. To ensure broad commercial equivalence, we intend to lower the statutory scheme payment percentages in 2020 to 7.4% and 2021 to 10.9% from 1 April 2020.

Summary of responses

2.6 The majority of respondents who expressed a view (**41**) agreed with the proposal to change the payment percentage, with 9 disagreeing.

2.7 Respondents in favour agreed it was reasonable to adjust the payments which would reduce the financial risk for companies if a price increase request was denied**.** They also said that the payment percentages should be monitored regularly in case of sudden growth.

2.8 Some concern was raised that smaller paying companies would still struggle to make the payment leading to supply constraints.

2.9 Respondents also raised concerns about the timing of the consultation**,** there was not time for companies to make an informed decision about which scheme to join before the window for joining the 2019VS closed at the end of December. However, it was recognised that there will always be a lag between consultation and implementing the new statutory payment percentages**.**

2.10 Some respondents suggested a more formal link between the voluntary and statutory schemes, or that Government should consider consulting on a formally defined methodology for setting payment percentages for the following year in the statutory scheme that would not require the making of new Regulations.

Government response

2.11 The Department recognises broad support for amending the payment percentages to ensure broad commercial equivalence between the schemes.

2.12 Furthermore, the Department notes that industry would prefer earlier notification of proposed changes to the statutory scheme. The Department had intended to begin consultation in December 2019. However, due to the unexpected general election that month, and the limitations on Government activities during pre-election periods, the consultation on changes could not be launched until January 2020.

2.13 It is also worth noting that the 2018 Regulations are clear that the annual review should take place by the end of March each year, and this is therefore the natural time to review whether they continue to meet the objectives of the scheme - and that includes consideration of the payment percentages. As such we believe undertaking the consultation at this stage does not run counter to the wording or spirit of the scheme.

2.14 Concerns were also raised about the financial risk for small companies, and potentially resulting supply shortages, if price increase requests are not accepted. Whilst these concerns are not directly related to this consultation, it is always helpful to hear the views of industry on such issues. The Department does take these risks seriously, and the 2018 Regulations include a price increase provision for this reason. The Department makes a decision on all price increase requests taking into consideration a number of factors including a company's margins and costs, supporting evidence and documentation which can include environmental or supply matters and the impact on affordability to the NHS.

3. Response on the level of the amended payment percentages

3.1 After review of the consultation responses, the Government has decided to proceed with reducing the payment percentage in 2020 from 14.7% to 7.4%. However, to take into account where companies have made payments at 14.7% under the 2018 Regulations in the first three months of the year, these companies will have a reduced payment percentage of 5% for the rest of the year. The payment percentage for all statutory scheme members will be 10.9% in 2021.

Q2: Do you agree or disagree with the levels at which we propose to set the statutory scheme payment percentages? Please give reasons to explain any comments

Q3: Do you have any comments on the proposed methodology used in determining the payment percentages (as set out in the impact assessment)? Please give reasons and provide any evidence or analysis that would support any refinement you think Government should make

Outline of consultation proposals

3.2 The proposed payment percentages for the statutory scheme are calculated using the growth of Measured Sales on an industry wide level (i.e. including 2019VS Measured Sales, statutory scheme Measured Sales and parallel import Measured Sales). This is the same process that is used to calculate the payment percentages for the 2019VS and the consistency of approach means that appropriate payment percentages are set across both schemes.

3.3 The details of the methodology for the calculation are set out in the accompanying Impact Assessment to this consultation. The Government believes that it is appropriate to continue to set payment percentages that are expected to control branded medicines growth at a rate of 1.1% each year.

3.4 In addition, the proposed payment percentages for the statutory scheme in 2020 and 2021 take account of the degree to which the 2019 payment percentage was set higher than required to control growth at 1.1% per annum, considering actual (rather than forecast) growth in Measured Sales. Using this approach ensures compliance of broad commercial equivalence with the 2019VS where overpayments are spread out over the lifetime of the scheme and enables both schemes to be in better alignment.

3.5 An alternative "do nothing" option of retaining the current payment percentages of 14.7% and 20.5% for 2020 and 2021 was also considered. However, this is expected to fail to allow growth at 1.1% per year and will not ensure broad commercial equivalence between both schemes. Therefore, this option has been discounted. It may also fail to facilitate the continued supply of medicines on reasonable terms, avoiding potential cost pressures on the NHS of medicines not being available on reasonable terms due to payment percentages set at a higher rate than required to control growth.

Summary of responses

3.6 Of the 45 respondents that expressed a preference, 27 welcomed the percentage change, while 18 respondents expressed concerns. A number of respondents made the following overarching comments on the payment percentages:

- Concerns over the Department's forecasting accuracy, including the impact of biosimilar and branded generic sales on growth.
- Respondents considered it was unfair that the payment percentage that applied to sales from frameworks and public contracts entered into between 1 April 2018 and 31st December 2018 to remain at 7.8%.
- Uncertainty of future payment percentages expose companies to further financial risks at the point of tendering for multi-year contracts or frameworks.
- The stated objective to balance the need to control branded medicines expenditure and achieve broad commercial equivalence with the voluntary scheme could not be achieved when the statutory scheme members are set to pay a higher rate than those in the voluntary scheme - i.e. 7.4% (aggregated) vs 5.9% for the voluntary scheme in 2020, and 10.9% vs (an estimated) 9% in 2021.

3.7 Some respondents raised issues outside the scope of the consultation. For example:

- That biosimilars and branded generics are exposed to competition and so natural market forces can control any excessive growth. Therefore, some respondents suggested both the statutory and voluntary schemes should apply only to originators that are not exposed to normal market forces of competition.

- That for plasma-derived products where the cost of production is generally high, tender prices may be raised to take account of the clawback of revenue resulting from the requirement to pay statutory scheme payment percentages.

Government response

3.8 It is the Secretary of State's responsibility to support the NHS in providing a high-quality comprehensive health service to patients. The statutory scheme safeguards the financial position of the NHS by constraining the costs of branded health service medicines through appropriate payment percentages. It ensures a level of spend on branded health service medicines that delivers value to taxpayers and NHS patients, while safeguarding the continuing supply of medicines to the health service on reasonable terms and taking account of industry 's costs in research and development.

Forecasting

3.9 The details of the forecast methodology were set out in Chapter 8 of the original consultation, and further detailed in the Consultation response published on 3 December 2018. These approaches used the best available data and insight available at the time to estimate future growth rates. The growth rates produced by this methodology were used in both the statutory and voluntary schemes.

3.10 The Department believes that it is appropriate to continue to use the same forecast growth rates across both the statutory and voluntary scheme in order to support the principle of broad commercial equivalence and avoid unwarranted divergence between the schemes. Furthermore, the Department continues to support payment percentages set in line with the 1.1% nominal allowed growth rate, with the annual review considering whether the scheme continues to meet its overall objectives.

Extant Frameworks and contracts

3.11 Some pharmaceutical companies are of the view that the payment percentage on extant frameworks and public contracts, which are set at 7.8% for relevant agreements entered into between 1 April and 31 December 2018, should also be lowered in line with these Regulations. However, sales under such agreements will have been entered into with full knowledge of the required payment percentage and that it would apply for its duration.

3.12 The Department clearly set out the payment percentage of 7.8% for such sales in the 2018 Regulations, which has remained fixed whilst payments on agreements entered into after 31 December 2018 have been subject to the higher payment percentage of 9.9% in 2019. The pricing of the relevant frameworks and public contracts would have factored in a 7.8% payment percentage for its duration and lowering it to match the new 2020 payment percentage level would unduly benefit the companies in question.

3.13 Companies who entered into agreements after 31 December 2018 are aware of the possibility that payment percentages might be revised and are therefore able to 'price in' this uncertainty in their tenders in the same way they are currently pricing in uncertainty around similarly variable input costs or exchange rates over the horizon of an agreement. Additionally, contracts and frameworks include annual review provisions which enable companies to apply for price variations where a significant change in external circumstances warrants this.

Scope of the regulations (biosimilars, branded generics, plasma-derived products)

3.14 Responses raised on these issues were out of the scope of this consultation and are therefore not considered as part of this response. The annual review, however, continues to consider whether the scheme is meeting its overall objectives.

4. Response to specific consultation requirements in the NHS Act

4.1 After a review of the consultation responses, the Government has updated the analysis of impacts of the proposals with the latest data on framework agreements. The Department did not receive new evidence or analysis from respondents as part of the consultation process.

Q4: Do you agree or disagree with the analysis in this Chapter, which is detailed further in the accompanying Impact Assessment, on: a) the impact of our proposals? b) the effect on those areas where the NHS Act 2006 requires we consider and consult?

Q5: Do you have any evidence that would help inform, and improve the quality of, our analysis?

Summary of responses

4.2 Respondents broadly approved of the analysis, with 17 and 20 respondents agreeing with part a) and b), while 8 and 10 disagreed respectively. Some continued to provide comments on the methodology the Government had used to set out the impact on the life sciences sector, the UK economy and NHS patients. The main points raised were:

- The link between changes in NHS income and changes in income for shareholders in pharmaceutical companies should be clarified.

- Some respondents highlighted impacts on supply issues suggesting there may be differential impacts across companies in the UK life sciences industry which may have consequences in reducing competition in the supply of certain medicines to NHS patients. This might reduce the pool of suppliers that can respond to a shortage. Respondents noted there were sporadic gaps or shortages in the supply of certain commonly used branded medicines (e.g. HRT, birth control, asthma, etc) and suggested analysis could be included of the factors that lead to these gaps and whether they are particularly sensitive to price changes or the effects of limiting price increases.

- When tendering for products supplied under framework agreements companies will simply increase their tender price to take account of any statutory scheme payment which increases the complexity of the tendering process for no gain.

- Some respondents also suggested further analysis of the ability of biosimilar and branded generic medicines to produce savings. This might include savings attributable to recent patent or exclusivity periods ending on originator products and the savings derived from existing biosimilar and branded generic markets.

Government response

4.3 The Department has sought to clarify any elements of the Impact Assessment that may have been unclear to respondents. The Impact Assessment also now includes the latest available data on framework agreements in revising its view of likely impacts of the proposals.

4.4 On supply issues, Government considers that there are already existing mechanisms to deal with supply risks and that the proposed changes to lower payment percentages are likely to actually help address risks of supply issues by ensuring that medicines are available on reasonable terms. Furthermore, whilst there may be differential impacts across firms depending on their individual portfolio of products, the statutory and voluntary schemes are designed to limit growth in sales of branded medicinal products in aggregate and to support the overall life sciences sector and wider economy.

4.5 On price increases, Government acknowledges that under certain circumstances, companies may need to apply for price increases, whether this is to address supply risks or in order to maintain profitability across their portfolio of medicines. Government has not seen evidence that any such price increases materially effect the level of growth in sales of branded medicines.

4.6 Government acknowledges the role that competition between biosimilars (including competition with off-patent biological originators) plays in delivering savings for the NHS. Government assumptions on the drop in expenditure resulting from patent expiry on both biological and non-biological medicines were set out as part of the analysis accompanying the 2018 consultation. However, given the decision to align forecast growth figures across both the statutory and voluntary schemes (as set out in the answer to Consultation Question 3) it is outside the scope of this consultation to provide further analysis on likely savings as a result of competition in these areas.

5. Response on statutory duties

Q6: Do you agree or disagree with our initial conclusions as to the impacts that the proposed changes to the statutory payment percentages will have on the statutory duties of the Secretary of State?

Q7: We welcome any comments, including any further evidence, that may assist us in further developing our assessment of the impact of the proposals in relation to the statutory duties of the Secretary of State

Summary of responses

5.1 The majority of the respondents were in agreement with the Governments initial conclusions on the proposed amendments' impact in relation to the Secretary of State's statutory duties. There was limited comment on potential improvements to our analysis on these duties. However, in respect of the Secretary of State's duty to promote a comprehensive health service earlier notice of proposed statutory scheme payment percentages would be helpful in order to allow more accurate setting of tender prices at the outset of the multiyear tender period.

Government response

5.2 The Department is confident that the proposals advance the Secretary of State's statutory duties, including the duty to promote a comprehensive health service. Some respondents argued that the Department should provide earlier notice of changes to the payment percentages to support the setting of tender prices at the outside of a multiyear tender. Whilst the Department acknowledges the benefits of setting multiple year percentages, having previously set the 2020 and 2021 payment percentages in order to try to limit the expected average growth rate to the agreed 1.1%, the payment percentages are re-calculated on an annual basis. The 2018 Regulations make provisions for future annual payment percentages based on current knowledge of the expected growth rate, however forecasts cannot always be accurate, as recognised by the reduced payment percentages set out in this consultation.

5.3 The Department remains of the view that, as set out in the 2018 consultation response published on 3 December 2018, companies are aware of the possibility that payment percentages might be revised and are therefore able to price in this uncertainty in their tenders in the same way they are currently pricing in uncertainty around similarly variable input costs or exchange rates over the horizon of an agreement.

5.4 The 2018 Regulations also include a price increase provision. The Department will review and make a decision on all price increase requests taking into consideration a number of factors, including a company's margins and costs, and any supporting evidence in respect of the market, clinical need, supply constraints, manufacturing, operational, research and development costs and impacts on the NHS budget.

5.5 We have considered biological medicines and believe that while biosimilar competition remains effective, the proposed payment percentages do not appear to have any adverse impact on competition.

Medicines and Pharmacy Directorate

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