Department of Health & Social Care

Annual Review of The Branded Health Service Medicines (Costs) Regulations

March 2020

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Review Summary

This is the annual review of The Branded Health Service Medicines (Costs) Regulations 2018 as set out in Section 29 of those Regulations.

This review considers the extent to which The Branded Health Service Medicines (Costs) Regulations 2018 (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 in a way that is consistent with supporting both the life sciences sector and the broader economy.

We have carried out a review of the 2018 Regulations and found out that the objectives of the Regulations have been achieved and remain appropriate.

The Department carried out the first review of the 2018 Regulations in 2019 and stated publicly in them our intention to continue to take into account broad commercial equivalence between the voluntary and statutory schemes when considering amendments to the Regulations. Broad commercial equivalence does not mean that both schemes need to be identical, as we are keen to ensure that companies have an effective choice of schemes. Our aim is to make both schemes work cohesively and in a complementary fashion to ensure that we continue to achieve the main objectives of the 2018 Regulations.

We will continue to review the 2018 Regulations in coming years to make sure they remain fit for purpose.

1. Aim and Scope of the Review

1.1 The 2018 Regulations set out in Section 29 that an annual review will be undertaken to assess the extent to which the objectives of the Regulations are being achieved. Section 29 states that:

29. - Annual Review

(1) Before the end of the review period, the Secretary of State must -

(a) carry out a review of these Regulations;

(b) set out the conclusion of the review in a report; and

(c) publish the report

(2) The report must in particular -

(a) set out the objectives intended to be achieved by the scheme established by these Regulations;

(b) assess the extent to which these objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(3) Under this Regulation, "review period" means the period of one year beginning on the date of the coming into force of these Regulations.

1.2 The Regulations that came into force on 1 April 2018. They moved the statutory scheme away from a system of price cuts to one where payments were based on a percentage of the value of the branded health service medicines sales by the relevant manufacturer (or companies) in addition to price controls. Amendments were subsequently made in December 2018 by The Branded Health Service Medicines (Costs) (Amendment) Regulations 2018 ("the Amendment Regulations"), with those amendments coming into force on 1 January 2019.

1.3 The Amendment Regulations changed the payment percentages in the 2018 Regulations; included all biological medicinal products (including biosimilars) within the scope of the health service medicines captured by the payment mechanism, price controls and information requirements; and changed the application of the payment system for sales of medicines supplied under a contract

with a contracting authority based on a framework agreement or under a public contract.

1.4 This review will focus on the objectives of the 2018 Regulations as amended by the Amendment Regulations.

2. Overview of the Regulations

2.1 The 2018 Regulations replaced the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2018 and the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007 as amended.

2.2 The principal change to the statutory scheme introduced by the 2018 Regulations was the introduction of a payment system, similar to the system operating in the 2019 Voluntary Scheme for Branded Medicine Pricing and Access (2019VS) - which was established on the same principles as the Pharmaceutical Price Regulation Scheme 2014 (2014 PPRS). The 2018 Regulations set a payment percentage for sales of relevant medicines at 7.8%, the same level applied to the 2014 PPRS. The Amendment Regulations, from 1 January 2019, amended the payment percentage to 9.9%, included additional medicinal biological products and changed the application of the payment percentage for sales of medicines supplied under a contract with a contracting authority based on a framework agreement or under a public contract.

3. Regulatory Amendments

3.1 In August 2018, the Department published a consultation on proposed changes to the statutory scheme. The December 2018 Response was then published on 3 December 2018 alongside the Amendment Regulations. All documents relating to the consultation and the response can be found on the consultation homepage.

3.2 The Amendment Regulations introduced a set of new payment percentages for the years 2019, 2020 and 2021, which were set at 9.9%, 14.7% and 20.5% respectively. In line with our regulatory obligations and public commitments, we reviewed the 2018 Regulations and these payment percentages to ensure that they remained appropriate.

3.3 During our review, we found that, to be able to achieve the objectives of the 2018 Regulations we needed to change the payment.

3.4 Accordingly, we consulted on new payment percentages from 21 January 2020 until 17 February 2020 and publish our consultation response simultaneously to this annual review.

3.5 It is the Government's responsibility to support the NHS in providing a high-quality comprehensive health service to patients, and to enable us to continue to do this, it is appropriate to set payment percentages that are expected to control branded medicines growth at a rate of 1.1% each year.

3.6 Following the consultation, we have decided to set the new payment percentages for 2020 and 2021 at 7.4% and 10.9% respectively. However, for companies that made payments at the rate of 14.7% in the first quarter of 2020, their new payment percentage rate will be 5.0% for the period of 1 April 2019 to 31 December 2019. These changes will come into effect from 1 April 2020.

4. Review Methodology

4.1 To control the prices of branded medicines all price applications for new medicines or requests for a price increase to an existing medicine are considered by the Branded Medicines Pricing Committee who rigorously review relevant financial and non-financial information when making a decision. Non-financial information includes such areas as clinical need, supply constraints, manufacturing, operational, research and development costs and impacts on the NHS budget. This year the Committee has considered c22 applications from statutory scheme companies of which 5 were for price increases.

4.2 To review the effectiveness of the 2018 Regulations in limiting the growth in costs of branded health service medicines, we have reviewed the growth of Measured Sales on an industry wide level, which covers 2019VS Measured Sales, statutory scheme Measure 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.

4.3 The Life Science Industrial Strategy set out the importance of a clear, stable, and innovative medicines access and pricing system to the UKs position as global life sciences hub. The successful delivery of the statutory scheme is an essential part of a wider drive to improve collaboration with industry, ensuring the best innovations get to patients as fast as possible whilst ensuring the affordability of the NHS. Through this package we are accelerating NICE approval timelines for all medicines, boosting the commercial capacity of NHSE with a new clear commercial framework, and providing additional support for those treatments providing the highest health gain to UK patients.

5. Assessment Against the Policy Objectives

5.1 As stated on several occasions, the Department considers that the main objectives of the statutory scheme 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.

5.2 We have considered the degree to which the scheme has delivered each of these objectives in more details below.

1. Limit the growth in costs of branded health service medicines to safeguard the financial position of the NHS.

5.3 The statutory scheme, together with the voluntary scheme, aims 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 to the health service on reasonable terms; the costs of research and development; and impacts on the UK life sciences industry, the wider economy and patients.

5.4 The new Regulations will introduce a new payment percentage of 5.0% for companies that made payments at the rate of 14.7% in Q1 2020, while others will pay the proposed rates of 7.4% for Q2 to Q4 2020. The new payment percentages will be effective from 1 April 2020. From 2021, companies will pay at a rate of 10.9%. Lowering the payment percentages would ensure better alignment with the 2019VS. 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.

5.5 These amendments ensure that the Department is not expecting to receive higher payments from statutory companies than is necessary to control allowed growth sales growth at 1.1%. Furthermore, using this approach also ensures 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.

5.6 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 to date in Measured Sales.

5.7 The following table sets out the number of companies making payments under the statutory scheme in each quarter from Q2 2018 (when the Regulations came into force) to Q4 2019. It also details Measured Sales and the resulting payments under the scheme. Measured Sales here refer to total sales of all branded health service medicines, including sales of presentations which are exempt from the payment mechanism.

Table 1: Number of companies, sales and payments

Quarter	Number of Companies	Measured Sales	Payment
Q2 2018	19	£237m	£3m
Q3 2018	21	£274m	£6m
Q4 2018	20	£336m	£12m
Q1 2019	22	£410m	£18m
Q2 2019	22	£427m	£20m
Q3 2019	22	£416m	£23m
Q4 2019	22	Not available	Not available

5.8 The number of companies making payments under the scheme remained broadly stable between Q2 and Q4 2018. Over the same period, Measured Sales increased from c.£237m in Q2 to c.£336m in Q4, and payments made to the Department increased from c.£3m to c.£12m. In Q1 to Q3 of 2019, there was an increase in the number of companies making payments to the Department.

5.9 Between Q4 2018 and Q1 2019 five companies which make payments joined the statutory scheme, and three left, resulting in 22 companies in the statutory

scheme, which has remained constant throughout 2019. These company moves contributed to increased levels of measured sales in 2019 compared to 2018, which was £416m in Q3 2019. Payments made to the department increased from £18m to £23m from Q1 to Q3 2019.

Table 2: Sales exempt from the payment mechanism

Quarter	Sales of low-cost presentations	Sales under Agreements - paying 0%	Sales under Agreements paying - 7.8% (2019 onwards)
Q2 2018	£2m	£197m	
Q3 2018	£2m	£191m	
Q4 2018	£2m	£177m	
Q1 2019	£2m	£219m	£52m
Q2 2019	£2m	£206m	£84m
Q3 2019	£2m	£167m	£80m

5.10 The overall Measured Sales in Q2 to Q4 2018 totalled c.£846m. This compares to measured sales in the calendar year 2017 of c.£1,000m, and c.£1,106m in 2016. However, an approximate estimate for 2018 full year sales of c.£1,128m can be obtained by uprating sales in Q2 to Q4 by four over three. While only providing an approximation, this estimate shows that the overall level of sales in 2018 under the statutory scheme is broadly in line with previous years.

5.11 As a consequence of the company movement between schemes, 2019 statutory scheme Measured Sales are substantially greater than in 2018. The latest estimate for measured sales in 2019 for the statutory scheme is £1,683m, which is derived from the calculation of growth comparing Q1-Q3 2018 sales to Q1-Q3 2019 sales for the specific companies in the statutory scheme as of 1 January 2019, regardless of what scheme they were in during 2018. This growth rate currently stands at 2.44%. For further information see the Impact Assessment which accompanies the 2020 consultation response.

5.12 Payments made to the Department have increased as a share of overall Measured Sales. This is because the share of Measured Sales exempt from the payment

mechanism has decreased between Q2 to Q4 2018 and Q1 to Q3 2019. Table 2 shows the value of sales exempt from the payment mechanism under the scheme's exemption provisions.

5.13 With sales under framework Agreements and public contracts only fully exempt from the payment mechanisms where they were entered into before 1 April 2018, agreements entered into between 1 April 2018 and 31 December 2018 pay 7.8%), the overall value of sales exempt on these grounds is falling over time. This is because Agreements end and are then replaced with new Agreements, sales under which are not fully exempt. Saying this, sales exempt from the payment mechanism were higher than anticipated in the impact assessments for the 2018 Regulations and the Amendment Regulations. This difference is due to the unpredictability of decisions on extensions of existing frameworks.

5.14 In addition to the sales made by companies included in Table 1 above, sales were made by companies which benefit from the small company exemption. These companies do not make payments, and do not provide quarterly sales and payment data. However, small companies subject to the scheme are required to submit actual sales data for their previous financial year in February 2020 (unless new to the scheme when the company provides a sales forecast for the current financial year). This data indicates that in total, small companies make sales of c.£92m per year. We note that this figure does not necessarily relate to the same 12-month period for all small companies, as companies have different financial years.

5.15 The overall sales in the scheme were higher than expected in our Impact Assessments. However, we note that the numbers presented here should not be taken as evidence on the overall growth rate of branded health service medicine sales, as the number of companies' subject to the statutory scheme is changing over time. A full assessment of the evolution of branded health service medicines sales therefore requires consideration of the entire market (including the voluntary scheme and parallel imports).

5.16 Having reviewed the 2018 Regulations against its objectives, we have found that current payment percentages were unsustainable to achieve the objectives of the Regulations as they would not be expected to allow growth in sales of branded medicines at the desired rate.

5.17 As outlined in the January 2020 consultation document and Government Response to the consultation, the provisions in the current 2018 Regulations required the application of a 9.9% payment percentage on qualifying sales in 2019 and payment percentages of 14.7% and 20.5% in 2020 and 2021 respectively. These figures were set in 2018 and were based on forecast NHS sales of branded health service medicines.

5.18 The proposed changes to the payment percentages of 7.4% and 10.9% for 2020 and 2021 respectively will ensure the continued functioning of the scheme. We consider that the continued, successful functioning of the scheme plays an important part in limiting the costs of branded medicines to the NHS, ensuring their availability while also taking into account the cost of research and development.

2. Ensure medicines are available on reasonable terms, accounting for the costs of research and development

5.19 Decisions on price applications for new products entering the market are taken based on a number of factors, including the costs of research and development. The proposed payment percentages of 7.4% and 10.9% respectively would have positive impacts on pharmaceutical companies since there will be increased revenues for companies. As such, these may help support the life sciences sector, protect supply of medicines to the NHS at affordable levels, benefitting patients and the wider health system.

5.20 However, based on the figures that companies have now provided to the Department, growth in the sales of branded health medicines between 2018 and 2019 was lower than forecast. Therefore, given the lower than forecast growth in NHS sales of branded health service medicines, Government considers that lowering the current payment percentages to 7.4% and 10.9% respective would ensure availability of innovative medicines to the NHS and patients.

5.21 We acknowledge that the cost of production for plasma derived products is high. However, in making decisions on medicine prices, the Department considers all the necessary factors involved in ensuring that blood plasma products can be available and be supplied to UK patients on reasonable terms and companies are not unduly disadvantaged. In 2018, two blood plasma products were granted price increase – demonstrating the Department's flexibility in responding to the unique circumstances of product manufacturers while supporting life sciences and the wider economy. We believe that the current flexible approach that the Department takes in deciding medicine prices would mitigate undue cost burdens on blood plasma manufacturers. In line with our public commitment, we will continue to review the 2018 Regulations to ensure they are fit for purpose by using evidence to make the necessary adjustments.

5.22 In our previous consultation response published on 3 December 2018, we said that we would review the impacts of the Regulations on products sold under Agreements including branded generics and biological medicines.

5.23 In regard to branded generics, (this review focuses on those branded generics that are required to have a brand name by the regulator) we acknowledge that these

types of products operate with some level of competition and so might be more price sensitive. Changes to the 2018 Regulations also meant that the payment percentages began to apply to sales of these products which is consistent with the 2019VS which also applies the payment percentage to these. Currently, we are not aware of any issues become aware of any issues related to the supply or pricing of such medicines.

5.24 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. In addition, tendering arrangements for biosimilar and biological medicines ensures competition across all the relevant medicines and applying payment percentages differently to such medicines for companies in the statutory scheme would have a distorting effect. We will continue to assess trends in the overall usage of branded generics, biological medicines and biosimilars on an annual basis.

5.25 The payment percentages of 7.4% and 10.9%respectively, which will come into force from 1 April 2020, will have positive impacts on pharmaceutical companies since there will be increased revenues for companies. As such, this may help support the life sciences sector, protect supply of medicines to the NHS at affordable levels, benefitting patients and the wider health system.

3. Deliver in a way consistent with supporting the life sciences sector and the broader economy

5.26 We believe that lowering the payment percentages will help support the life sciences sector and the broader economy.

5.27 As set out in all consultations and responses (both in 2018 and 2020) on the statutory scheme, the scheme is part of a broader set of measures with which the Government seeks to create an environment where clinically-cost-effective medicines are supplied at an affordable cost, in a way consistent with supporting both the life sciences sector and the broader economy.

5.28 The Government's Response to the proposed amendments to the 2018 Regulations, which is published with this annual review, and the accompanying Impact Assessment, considered in detail the expected impacts on the life sciences sector and the broader economy. We think that changes to the payment percentages will ensure continued functioning of the statutory scheme. This would achieve the objective of limiting the costs of branded medicines, ensuring their availability which is consistent with supporting the life sciences sector and the broader economy.

5.29 The proposed amendments will have the effect of ensuring a suitable commercially viable option for companies if they choose not to join the 2019VS. The 2019VS operates alongside the statutory scheme. The 2019VS enabled the UK pharmaceutical industry to co-create regulation governing the majority of all branded medicines sales in the UK, and the effective operation of both schemes means that the Department can continue to receive an appropriate amount in payments from industry. Those payments are allocated to the health service across the UK and used in the best interest of patients.

Summary

5.30 In summary, the available evidence suggests that the amendments to the Regulations, which will come into force on 1 April 2020, will ensure continued supply of medicines on reasonable terms which will be of benefit to the UK population. This would in turn avert potential cost pressures or health disbenefits for patients and the NHS of medicines not being available at reasonable terms.

6. Broad Commercial Equivalence Between the Schemes'

6.1 The 2019VS includes a mechanism to revise future payment percentages in line with actual growth, but the Statutory Scheme features fixed payment percentages as set out in the amended 2018 Regulations.

6.2 In the 2018 consultation on previous amendments to the statutory scheme, made from 1 January 2019, the Government set out how it would apply a principle of broad commercial equivalence between the two schemes. One element of this is ensuring some alignment between the two schemes' payment percentages.

6.3 The payment percentage for the 2019VS for 2020 is 5.9%. This figure is derived using formulae in the 2019VS document and is based on the latest financial data companies provide to the Department. To ensure commercial equivalence with the 2019VS, the Government will introduce new payment percentages (7.4% in 2020 and 10.9% in 2021) for the statutory scheme and believes these to be appropriate in controlling growth in branded medicines sales.

6.4 The 2019VS includes a number of exemptions that mirror those in the statutory scheme (e.g. OTC presentations, parallel imports, sales of companies with annual sales of branded health service medicines below £5m). There are further exemptions for exceptional central procurements as well as centrally procured medicines. The voluntary scheme includes exemptions which exclude products from application of the payment percentage but include the same products in the calculation of medicines growth for setting the payment percentage (sales of medium sized companies and new active substances (NAS)). There are, however, no exemptions from the payment mechanisms in the 2019VS for sales under framework Agreements or public contracts (i.e. payment systems for sales of medicines supplied under a contract with a contracting authority based on a framework agreement or under a public contracts).

6.5 The allowable growth rate for the 2019VS is set at 2.0% per annum.

6.6 The allowable growth rate for the Statutory Scheme is 1.1% per annum, which was originally based on the average allowed growth rate for the 2014 PPRS. Given that this level of allowed growth does not appear to have created any supply issues and because actual growth in measured sales in the first three quarters of 2019 was also 1.1%, the Department believes that this allowed growth rate remains appropriate.

6.7 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 usual to control growth at 1.1% per annum, considering actual (rather than forecast) growth in measured sales. Using this approach ensures broad commercial equivalence with the 2019VS where overpayments are spread over the lifetime of the scheme. This approach enables both schemes to be in better alignment.

6.8 Broad commercial equivalence does not mean that both schemes need to be identical, as we are keen to ensure companies have an effective choice of schemes. Our aim is to make both schemes' work cohesively and in a complementary fashion to achieve the broader objectives of the schemes.

6.9 To ensure the voluntary and statutory schemes continue to work in tandem to achieve their objectives, we will continue to take into account any changes to the voluntary scheme that could impact on broad commercial equivalence between the two schemes.

7. Legal Duties

7.1 As part of the Statutory Scheme consultation published on 21 January 2020 we included an assessment of Statutory duties. These include consideration of the Secretary of State’s duties under the NHS Act 2006, the Public Sector Equality Duty and the family test.

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Medicines and Pharmacy Directorate

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