Department of Health & Social Care

Annual Review of The Branded Health Service Medicines (Costs) Regulations 2018

29 March 2019

Contents

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 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.

In summary, we find that the 2018 Regulations have achieved these objectives, that these objectives remain appropriate, and that no system imposing less regulation could currently achieve them. As such, we do not propose any changes to the regulations at this point.

After the Department consulted on, and made decisions with respect to the amendments to the 2018 Regulations which came into force on 1 January 2019, Government and the ABPI agreed a new voluntary scheme, which went live in January 2019. Considering the provisions of this voluntary scheme, the Department believes the statutory scheme under the 2018 Regulations, as amended, to be broadly commercially equivalent to the voluntary scheme. In the future, the Department will take into account broad commercial equivalence of both schemes when making changes to the 2018 Regulations.

1. Aim and Scope of the Review

1.1 The Branded Health Service Medicines (Costs) Regulations 2018 ("the 2018 Regulations") set out in Section 29 that a review will be undertaken to assess the extent to which the objectives of the 2018 Regulations are being achieved. This review should be reported within one year of the Regulations coming into force. Section 29 states:

> 29.— Annual review
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> (1) Before the end of the review period, the Secretary of State must—
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> (a) carry out a review of these Regulations;
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> (b) set out the conclusions of the review in a report; and
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> (c) publish the report.
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> (2) The report must in particular—
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> (a) set out the objectives intended to be achieved by the scheme established by these Regulations;
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> (b) assess the extent to which these objectives are achieved; and
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> (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.
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> (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 2018 Regulations came into force on 1 April 2018 and amendments were subsequently made in December 2018 ("the Amendment Regulations"), with those amendments coming into force on 1 January 2019.

1.3 The Department's consultation response titled "Proposed changes to the statutory scheme to control the costs of branded health service medicines", published on 3 December 2018 ("the December 2018 Response"), stated: "There will be an annual review of the Regulations no later than April 2019 to consider, based on the available data, whether the changes introduced in April 2018 and January 2019 are delivering the Government’s objectives for the statutory scheme."

1.4 This review will, however, focus in the main on the 2018 Regulations before the Amendment Regulations. This is because the Department receives data from scheme members on a quarterly basis in arrears. As such, the first set of quarterly data for 2019 will not be available until after this report must be published.

2. Overview of the Regulations

2.1 The Branded Health Service Medicines (Costs) Regulations came into force on 1 April 2018, replacing the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008 ("the 2008 Regulations"), and the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007 ("the 2007 Regulations"), 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 voluntary scheme since the commencement of the Pharmaceutical Price Regulation Scheme 2014 (2014 PPRS). The payment percentage applying to sales of relevant medicines was set at 7.8%, the same level as the payment percentage for the 2018 calendar year operational in the 2014 PPRS. The payment system included a number of exemptions, which applied to sales of:

- Over-the-counter (OTC) branded medicines;
- Sales of medicines supplied under a contract with a contracting authority based on a framework agreement or supplied under a public contract (together, "Agreements") where the relevant Agreement was entered into on or before the coming into force of the 2018 Regulations;
- Low cost presentations;
- Parallel imports; and
- Sales of companies with sales of branded health service medicines of less than £5m during the most recent complete calendar year.

2.3 In addition, changes were made to the regulatory provisions for maximum prices to reverse the price cut applied under the 2007 and 2008 Regulations, as well as changes to the information requirements, which were largely consequential to the introduction of a payment mechanism.

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 In summary, the Amendment Regulations introduced the following changes to the 2018 Regulations from 1 January 2019:

(a) A set of new payment percentages for the years 2019 to 2021 was set out in regulations. These payment percentages have been derived from a methodology for calculating payment percentages based on the difference between the expected growth rate of Branded Health Service Medicines sales and an allowed growth rate. Payment percentages for the years 2019 to 2021 were set at 9.9%, 14.7%, and 20.5%, respectively;

(b) The definition of relevant medicines was extended to include all biological medicinal products, including those marketed under a combination of International Non-Proprietary Name (INN) and company name; and

(c) The treatment of sales of medicines supplied under Agreements was changed, with sales under Agreements entered into on or before 1 April 2018 retaining their exemption from the payment percentage, sales under Agreements entered into between 2 April 2018 and 31 December 2018 being subject to a payment percentage of 7.8% for the duration of the Agreement, and sales under Agreements entered into after 31 December 2018 subject to whatever payment percentage is set out in the 2018 Regulations, including any future changes of payment percentages as a consequence of reviews of the regulations.

4. Review Methodology

4.1 To review the effectiveness of the 2018 Regulations we have analysed, evaluated and assessed what we consider to be the best available data relating to the statutory scheme for the period April 2018 to March 2019.

4.2 With the 2018 Regulations coming into force on 1 April 2018, only a limited amount of data is available to assess the impact of the changes introduced to the statutory scheme. The main data sources for this review are the data made available to the Department through company returns as part of the operation of the payment system, alongside additional data collected such as price increase applications, and information around the discontinuation of medicines.

4.3 In addition to our assessment against the policy objectives of the statutory scheme, we have also considered the issue of broad commercial equivalence between the statutory scheme and the 2019 Voluntary Scheme for Branded Medicines Pricing and Access (2019 Voluntary Scheme). At the time of our December 2018 consultation response, a final agreement on the voluntary scheme had not been reached.

5. Assessment Against the Policy Objectives

5.1 Consistent with what is stated in the consultation documents and responses to the consultations on the 2018 Regulations and the Amendment Regulations, the Department considers that the aims and 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 detail below.

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 2018 Regulations introduced a payment mechanism, and a payment percentage of 7.8%, on sales of branded health service medicines in scope of the statutory scheme, effective from 1 April 2018. This change was made, in part, to re-establish a level of alignment with the voluntary scheme that was lost with the 2014 Pharmaceutical Price Regulation Scheme (PPRS), which worked on the basis of a payment mechanism. The payment percentage of 7.8% was aligned to the payment percentage applicable in the 2014 PPRS for the calendar year 2018.

5.5 The Amendment Regulations increased this payment percentage to 9.9% from 1 January 2019, changed the treatment of sales under Agreements, and clarified the treatment of biological medicines, including those sold under a combination of INN and company name, as outlined in Section 3 above.

5.6 The following table sets out the number of companies making payments under the statutory scheme in each quarter from Q2 2018 to Q1 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. We note that data relating to Q2 2018 and later is currently unaudited, and therefore subject to change following audit.

Table 1: Number of companies, sales, and payments by quarter

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	Not available	Not available

5.7 The number of companies making payments under the scheme remained broadly stable between Q2 and Q4 2018, at around twenty companies. 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.

Table 2: Sales exempt from the payment mechanism

Quarter	Sales of low cost presentations	Sales under Agreements
Q2 2018	£2m	£197m
Q3 2018	£2m	£191m
Q4 2018	£2m	£177m

5.8 Overall measured sales in Q2 to Q4 2018 therefore came to c.£847m. This compares to measured sales in the calendar year 2017 of c.£1,000m, and c.£1,106m in 2016. Because the 2018 Regulations only came into force on 1 April 2018, the Department has not received financial returns from companies for Q1 2018, and therefore a direct year-to-year comparison of 2018 with previous years is clearly not possible. However, a rough estimate for 2018 full year sales of c.£1,129m 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 under the statutory scheme is broadly in line with previous years.

5.9 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 and Q4 2018. Table 2 shows the value of sales exempt from the payment mechanism under the scheme's exemption provisions.

5.10 With sales under Agreements only exempt from the payment mechanisms where an Agreement was entered into on or before 1 April 2018, 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 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.

5.11 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. As these companies do not have to make payments, no quarterly sales and payment data is available. Small companies subject to the scheme submitted sales forecasts for their current financial year in February 2019. These forecasts indicate that in total, small companies make sales of c.£93m 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.

5.12 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).

5.13 In summary, data on sales and payments under the scheme shows that the scheme has helped to limit the growth in the cost of branded health service medicines to the NHS in line with its objectives over the three quarters since April 2018.

5.14 While financial returns are not yet available for Q1 2019, the number of companies making payments under the statutory scheme has remained stable compared to 2018, actually increasing by two compared to the previous quarter.

5.15 As the payment percentages and allowable growth rate for the scheme were updated in the Amendment Regulations on 1 January 2019, and the Department receives data from scheme members on a quarterly basis in arrears, the first set of quarterly data for 2019 will not be available until after this review is published. As such we do not believe that it is possible to properly assess the ongoing appropriateness at this point. The Department will, as part of the ongoing operation of the voluntary scheme, calculate growth rates of branded health service medicine sales across the voluntary and statutory schemes as well as parallel imports. We will take this as an opportunity to review the ongoing appropriateness of payment percentages and allowed growth rate for the statutory scheme, and consult on changes where necessary.

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

5.16 As outlined in our August 2018 consultation and the December 2018 Response, the payment mechanism in the statutory scheme was designed with explicit consideration of any potential impacts on the availability of medicines to the UK market, as well as the costs of research and development. These considerations directly influenced the choice of the allowable growth rate for the statutory scheme.

5.17 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. We remain of the view that where the overall pricing mechanism would make supply of specific existing products to the UK market unviable, the price increase mechanism set out in the 2018 Regulations provides an appropriate tool to ensure availability of these medicines while giving consideration to costs of research and development, amongst other factors.

5.18 In 2018, five price increase applications were granted to companies, with an average price increase of c.18%. The number of price increases granted was broadly in line with numbers for previous year - in 2016, five price increases were granted, while in 2017, three price increases were granted. The magnitude of price increases also shows that reasons other than the introduction of the payment system played a role for the affected products, as all price increases were larger than the impact of the payment percentage.

5.19 Two of the products for which price increases were granted in 2018 were blood plasma products. This confirms our view set out in the December 2018 response that the price increase mechanism presents a viable mechanism for manufacturers

of blood plasma products to ensure adequate supplies of these products are available to the UK market.

5.20 The limited number of price increases shows that the introduction of the 2018 Regulations, and its payment mechanism, has not led to widespread upward pressure on prices. While at the same time the price increase provision is being used by companies and the Department to flexibly respond to any issues arising for specific products.

5.21 In our December 2018 Response, we explicitly said we would review the impacts of the 2018 Regulations and Amendment Regulations on products sold under Agreements as well as biological medicines.

5.22 We do not believe that at this early stage it is possible to reach reliable conclusions about the impact of these Regulations on sales of products under Agreements. At the point of writing, only 9 months of data from 1 April 2018 are available. Furthermore, with most Agreements lasting for a period of two to four years, the majority of such sales are still made under Agreements entered into before the coming into force of the 2018 Regulations, and continue to be exempt from application of the payment percentage.

5.23 We have reviewed data on product discontinuations for the wider medicines market, as well as for biological medicines specifically, since the coming into force of the Amendment Regulations. While the Department cannot disclose details of discontinuations for reasons of commercial sensitivity, the level of discontinuations was in line with previous years, and the reasons cited by companies were unrelated to the introduction of the 2018 Regulations or the wider medicines pricing arrangements. We will assess trends in the overall usage of biological medicines and biosimilars on an annual basis.

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

5.24 As set out in previous consultations and responses 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- and cost-effective medicines are supplied at an affordable cost, in a way consistent with supporting both the life sciences sector (including research and development) and the broader economy.

5.25 The Government's December 2018 Response to the consultation on the Amendment Regulations, as well as the accompanying Impact Assessment, considered in detail the expected impact of the Amendment Regulations on the life sciences sector and the broader economy.

5.26 Since publication of our consultation response in December 2018, negotiations on a successor to the 2014 PPRS were successfully concluded, and the 2019 Voluntary Scheme now operates alongside the statutory scheme. The voluntary scheme enabled the UK pharmaceutical industry to co-create regulation governing the majority of all branded drugs sales in the UK, and we therefore believe that the statutory scheme in its current form is consistent with a joint approach to regulating medicines pricing and access with the life sciences industry.

5.27 As outlined in the section on measured sales and payments above, the 2018 Regulations have resulted in c.£21m in payments from companies subject to the statutory scheme in Q2 to Q4 2018. These savings are re-invested in the wider NHS, thereby delivering wider economic benefits through increased patient health as outlined in the Impact Assessments for the 2018 Regulations and the Amendment Regulations.

5.28 With the 2018 Regulations coming into force on 1 April 2018, the Amendment Regulations coming into force on 1 January 2019, as well as the 2019 Voluntary Scheme going live on the same date, we do not believe that at this early stage it is possible to analyse potential impacts on the life sciences sector in the UK.

Summary

5.29 In summary, the available evidence suggests that the 2018 Regulations and have achieved their objectives, and we therefore do not believe that changes to the Regulations are required at this point.

5.30 We continue to believe that the objectives of the 2018 Regulations and Amendment Regulations remain appropriate, and that they are necessary to ensure these objectives can be achieved. We do not think that the same objectives could be achieved with as system that imposes less regulation at this point in time.

6. Broad commercial equivalence between schemes

6.1 The 2018 Regulations set a payment percentage equal to the payment percentage operating in the 2014 PPRS for the calendar year 2018. This was done explicitly with a view to creating a level of alignment between statutory and voluntary schemes.

6.2 At the point of publishing the Amendment Regulations, no final agreement had been reached on a successor agreement to the 2014 PPRS. As such, the question of broad commercial equivalence was not considered in the Government's December 2018 Response.

6.3 Following the Department's consultation and decisions on the Amendment Regulations, Government and the ABPI reached agreement on a new voluntary scheme, the 2019 Voluntary Scheme for Branded Medicines Pricing and Access.

6.4 The 2019 Voluntary Scheme continues the operation of a payment mechanism similar to the mechanism operating in the 2014 PPRS and in the statutory scheme. The payment percentage in the voluntary scheme was set at 9.6% for the calendar year 2019, and a calculation methodology has been agreed to update payment percentages throughout the lifetime of the scheme.

6.5 The voluntary scheme includes a number of exemptions which 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 vaccines. Furthermore, 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 is no exemption from the payment mechanism for sales under Agreements.

6.6 The allowable growth rate for the voluntary scheme is set at 2.0% per annum.

6.7 Considering the 2019 Voluntary Scheme in the round, we believe that its provisions make it broadly commercially equivalent to the statutory scheme, in line with our reasoning set out in the 2018 consultation response. This reasoning includes that a design principle of broad commercial equivalence is consistent with some differences in the application of the payment percentage to particular types of products, the overall payment percentage or growth rate and wider aspects of

pricing and access which are within the remit of the voluntary scheme but not the statutory scheme.

6.8 As no payments have been made by companies under either the statutory scheme following the coming into force of the Amendment Regulations, or the 2019 Voluntary Scheme, it is not yet possible to assess the real world impact of broad commercial equivalence on this basis. Data from before 2019 would not be informative about equivalence of the schemes, given the changes made to both schemes in January 2019.

6.9 We believe that companies' experience of the 2019 Voluntary Scheme and the amended 2018 Regulations demonstrate that there is differentiation between the schemes, as both schemes continue to operate with a significant number of companies and sales volumes. The Department will continue to monitor membership of both schemes and switching between schemes.

6.10 To ensure the voluntary and statutory schemes continue to work in tandem to achieve their objectives, we will also 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 A full and considered assessment of the Secretary of State's legal duties with regard to the NHS Act 2006, the Public Sector Equalities Duties and the Family Test was undertaken as part of the consultation for the Amendment Regulations and the December 2018 Response. We consider that those documents set out the implications and effects on the Secretary of State's duties, and continue to be relevant with regard to this annual review.

8. Recommendations and Conclusions

8.1 In light of the findings of this annual review, as well as the changes to the 2018 Regulations that came into force on 1 January 2019, we are not proposing to make further changes to the 2018 Regulations at this point.

8.2 The Department will continue to monitor the degree to which the 2018 Regulations continue to achieve their objectives on an ongoing basis. Should a future review identify a requirement for changes to the statutory scheme, these changes would of course be subject to consultation during which companies and other stakeholders can express their views on any proposed amendments to the 2018 Regulations.

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