Department of Health & Social Care

Annual Review of Regulations:

The Health Services Health Service Products (Provision and Disclosure of Information) Regulations 2018 and The Health Service Medicines (Price Control Penalties and Price Control Appeals Amendment) Regulations 2018

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1. Review Summary

1.1 This is the annual review of The Health Service Products (Provision and Disclosure of Information) Regulations 2018 and The Health Service Medicines (Price Control Penalties and Price Control Appeals Amendment) Regulations 2018.

1.2 This review considers the extent to which the Regulations have achieved their objectives. In summary, we find that both sets of Regulations have achieved their objectives, that the objectives remain appropriate, and that no system imposing less regulation could currently achieve them.

The Health Service Products (Provision and Disclosure of Information) Regulations 2018

2. Aim and Scope of the Review

2.1 Regulation 36 of the Health Service Products (Provision and Disclosure of Information) Regulations 2018 requires the Secretary of State to carry out an annual review of the Regulations and publish a report with the conclusion of the review which must:

1. Set out the objectives intended to be achieved by the Regulations;

2. Assess the extent to which the objectives are being achieved;

3. Assess whether those objectives remain appropriate; and

4. Assess the extent to which objectives could be achieved in another way which involves less onerous regulatory provisions.

3. Overview of the Regulations

3.1 The Health Service Medical Supplies (Costs) Act 2017 Act amended the NHS Act 2006 to give the Secretary of State the power to make regulations requiring anyone manufacturing, distributing or supplying UK health service products to record, keep and provide information about those products. Such information may only be collected for the purpose of enabling or facilitating:

- The remuneration/payment of NHS chemists and primary medical service

providers in, or in any part of, the UK;

- The availability of products in, or in any part of, the UK and the assessment of

whether the products represent value for money;

- The cost control powers in the 2006 Act.

3.2 The Health Service Products (Provision and Disclosure of Information) Regulations 2018 entered into force on 1 July 2018. The main purpose of these Regulations is to require persons who manufacture, distribute or supply any UK health service products to record, keep and provide information to the Secretary of State about the purchase, supply, price or availability of those products. They also require marketing authorisation holders to inform the Secretary of Stater about any shortages and discontinuations of medicines.

4. Review Methodology

4.1 To review the effectiveness of the Regulations we have analysed, evaluated and assessed what we consider to be the best data relating to information collection from the period July 2018 to June 2019.

4.2 A limited amount of data is available to assess the impact of the changes introduced by the regulations as the Regulations only came into force in July 2018 and do not affect companies covered under voluntary arrangements, which end in 2018 and 2019. The main data available is the returns through the quarterly information collection of generic medicines and special medicinal products through NHS Digital.

5. Assessment against the policy objectives

5.1 As noted above, these regulations require persons who manufacture, distribute or supply any UK health service products to record, keep and provide information to the Secretary of State about the purchase, supply, price or availability of those products. They also require marketing authorisation holders to inform the Secretary of Stater about any shortages and discontinuations of medicines. All information is requested and used only for the statutory purpose in the Health Service Medicines Supplies (Cost) Act as outlined under Three.

Objective 1: To improve the robustness of the community pharmacy reimbursement arrangements by requiring all suppliers to provide quarterly sales and purchase information

5.2 The Regulations require all manufacturers, importers and wholesalers of unbranded generic medicines (Part 2 of the Regulations) and special medicinal products (Part 3 of the Regulations) to provide the Department of Health and Social Care with information about their sales and/or purchases of such medicines every quarter.

5.3 These requirements replace voluntary agreements with industry: Scheme M with manufacturers of generic medicines, Scheme W with wholesalers of generic medicines and the Memorandum of Understanding (MoU) on Specials with manufacturers of specials. The rationale for moving to Regulations was that:

a) Under the voluntary arrangements, information was provided only by those manufacturers and wholesalers of unbranded generic medicines and special medicinal products that had signed up to the voluntary arrangements;

b) The purpose for which the information obtained under the voluntary arrangements could be used was restricted to informing community pharmacy reimbursement arrangements.

5.4 The Regulations provided for transitional provisions for UK producers who provided information on a voluntary basis under Schemes M, Scheme W and the MoU allowing them to provide information under the voluntary scheme until the relevant scheme ends. Scheme W ended on 31 December 2018, Scheme M ended on 30 June 2019 and the MoU will end on 31 July 2019.

5.5 Community pharmacies and primary services providers are reimbursed for the costs of every medicine they dispense. Reimbursement prices are published in the monthly Drug Tariff. There are three Drug Tariffs in the UK: one for England and Wales (made by the Secretary of State and the Welsh Government), and one each for Scotland and Northern Ireland. All three are constructed in a similar way, drawing where appropriate on similar market intelligence.

5.6 Community pharmacies earn margin on the products they dispense. Margin is the difference between the price they purchase at and the reimbursement price. In England, community pharmacies are allowed to earn £800 million every year. Any over or under delivery is usually corrected by amending reimbursement prices in Category M, the most commonly dispensed generic medicines.

5.7 The information provided under the Regulation by all manufacturers, importers and wholesalers enables the Department to improve the robustness of the community pharmacy reimbursement arrangements by basing reimbursement prices in England on information from the whole market instead of only part of the market (i.e. those who provided information voluntarily).

5.8 In addition, this information enables the Department to consider basing more reimbursement prices on actual sales and purchase information, subject to consultation with the Pharmaceutical Services Negotiating Committee (PSNC). Previous voluntary schemes did not provide for information collection on sales and purchase information for some drugs.

5.9 The data collected by the Department has improved since the Regulations entered into force:

- For generic medicines:

o The number of manufacturers that provide quarterly information has increased threefold (from 18 to 53) and the number of wholesalers has increased nine-fold (from 7 to 65).

o The number of generic medicines included in the quarterly collection has increased from 1,046 before the Regulations came into force to 2,732.

o Market coverage of manufacturer’s quarterly information has increased from about 70 percent of dispensed volume under the voluntary arrangements to about 90 percent of dispensed volume under the Regulations.

o Market coverage of wholesaler’s quarterly information has increased from under 60 percent of dispensed volume under the voluntary arrangements to nearly 80 percent of dispensed volume under the Regulations.

- For special medicinal products:

o The number of manufacturers that provide information has increased nearly fourfold (from 7 to 26) and wholesalers are now also providing information about these products (from zero to 26).

o The number of special medicinal products included in the collection has increased from 468 products to 594 (including tablets and capsules).

5.10 Work is ongoing to ensure that all manufacturers, importers and wholesalers who should provide information, do so. It is expected that the number of companies providing information will further increase over the next year.

5.11 As more information is obtained from more producers, the information in the Drug Tariff becomes more representative of the whole market. The Department is considering basing more reimbursement prices upon actual sales and purchase data and is developing proposals for this. Currently, only those drugs classed in Category M are reimbursed on a calculation using the average selling price. There are several benefits to community pharmacy that reimbursement prices better reflect market prices, including:

- The improvement of distribution of margin so that all community pharmacies benefit equally from margin; and

- The improvement of cash flow of community pharmacies because less adjustments are required to ensure delivery of the £800 million margin.

5.12 The information obtained under the Regulations helps the Department achieve its policy objective to improve the robustness of the community pharmacy reimbursement arrangements by requiring all manufacturers, importers and wholesalers to provide information. The Department relies on this information to inform the community pharmacy reimbursement arrangements and the policy objective therefore remains appropriate.

Objective 2: To improve the robustness of the process for setting concessionary prices in England by requiring all suppliers to provide volume and price information

5.13 The Regulations require manufacturers, importers and wholesalers, within two working days, to provide volume and price information to support the process for setting concessionary prices in England (regulation 27). When community pharmacies cannot source a medicine at or below the reimbursement price for that

medicine as set out in the Drug Tariff, the Department can introduce a concessionary price at the request of the PSNC.

5.14 Before the Regulations entered into force, this information was obtained on a voluntary basis from a small number of companies. Information is currently obtained monthly from 80 companies in contrast to 48 companies before the Regulations entered into force. Work is ongoing to increase the number of companies that provide information.

5.15 Volume and price information from more manufacturers, importers and wholesalers has made the Department's concessionary price setting process more robust. Concessionary prices that better reflect the market helps to ensure that community pharmacies are paid fairly, if prices suddenly go up, and patients continue to get their medication.

5.16 The information obtained under the Regulations helps the Department achieve its policy objective to improve the robustness of the concessionary price setting process by requiring all manufacturers, importers and wholesalers to provide information. There is a continued need for the Department to set concessionary prices, so the policy objective remains appropriate.

Objective 3: To require information to be kept about sales and purchases of medicines, appliance and borderline substances.

5.17 The Regulations require all manufacturers, importers and wholesalers, and anyone supplying to patients otherwise than by sale, to record and keep information about sales and/or purchases of medicines, appliances and borderline substances used by the National Health Service in England, Wales, Scotland or Northern Ireland (Part 4 of the Regulations). The period for which the information must be kept is 4 years. The Department can ask for this information to be provided for any of the statutory purposes in the Health Service Medical Supplies (Costs) Act 2017.

5.18 Part 2 and 3 require manufacturers, importers and wholesalers to provide information every quarter about any generic medicine or special medicinal product already listed with a reimbursement price in the Drug Tariff. In the same quarterly collection, information has been requested under Part 4 about generic medicines and special medicinal products that are not yet listed with a reimbursement price in the Drug Tariff but that are being considered for listing. It is expected that in the next year the Department will increase the number of ad-hoc requests under Part 4.

5.19 A comparison with the situation before the legislation entered into force cannot be made as the Secretary of State did not previously have the power to require companies to provide this information.

5.20 The information obtained under the Regulations helps the Department achieve its policy objective to improve the robustness of the community pharmacy reimbursement arrangements by requiring all manufacturers, importers and wholesalers to provide information about generic medicines and special medicinal products not already listed with a reimbursement price in the Drug Tariff. The Department relies on this information to inform the community pharmacy reimbursement arrangements and the policy objective therefore remains appropriate.

Objective 4: To enable the Secretary of State to request information about costs incurred with the manufacture or distribution of medicines and appliances.

5.21 The Regulations require manufacturers, importers and wholesalers to provide information on the costs incurred in connection with the manufacture and distribution of health service products (Part 5 of the Regulations). The information requested is information that a UK producer can reasonably be expected to record and keep for the purpose of understanding their own relevant costs. Where this information is in connection with a particular presentation of a medicine or appliance (as opposed to overall costs) an information notice must be issued requesting that information. The notice must state the statutory purpose for which the information is requested and a producer can appeal such a notice. An information notice would be used, for example, if the Secretary of State investigated a potentially unreasonably high price of a generic medicine and would like to understand whether the cost of manufacturing that medicine bears any relation to the price that it is sold at.

5.22 No cost information has been requested so far. The Department is however developing proposals to address high priced generics and understanding the cost of manufacturing and other costs will be central to those proposals. Part 5 of the Regulations will support those proposals and as such the policy objective remains appropriate.

Objective 5: To support the Department's management of supply issues by requiring Marketing Authorisation Holders to provide information about on discontinuation and anticipated supply shortages.

5.23 The Regulations require manufacturers or marketing authorisation holders to notify the Department of their plans to discontinue the manufacture of any health service medicine and of any anticipated supply shortages of health service medicines (Part 6 of the Regulations). This legal requirement replaced voluntary guidelines with the industry under which the Department estimated that only about half of all supply shortages were notified. This requirement entered into force in 1 January 2019 and supporting guidance for industry has been published on gov.uk . The Department can also require manufacturers, importers and wholesalers to provide information about available volumes when there is a supply shortage.

5.24 The introduction of the Regulations has increased both the quality and quantity of information provided on supply shortages and discontinuations. This supports the Department in its role of managing supply issues and mitigating the impact on patients. Most supply issues do not have an impact on patients because mitigation measures are put in place by the Department. More information, and more timely information, mean that the Department can put these timely measures in place to ensure that patients are not impacted or if that is not possible, to minimise the impact on patients. As such, the information obtained under the Regulations helps the Department achieve its policy objective to have better information to support its work to manage supply shortages and mitigate the impact on patients. There is an ongoing need for managing supply shortages and therefore the policy objective remains appropriate.

6. The extent to which the objectives could be achieved with less regulation

6.1 As outlined above, the Health Service Products (Provisions and Disclosure of Information) Regulations 2018 introduced a range of statutory duties on actors in the supply chain to record and provide information, either on request or routinely. The Department considers that the Regulations are proportionate and that the objectives could not currently be achieved with less onerous regulatory provisions. We believe that this is the case for two reasons.

6.2 Firstly, the Regulations were brought forward because previous arrangements were voluntary and only applied to those companies that had signed up to them, and restricted the use of the information. This applies to objectives one, two and five. The Regulations are necessary and proportionate in helping ensure that information is obtained from more companies than was the case under the voluntary arrangements. This improves the community pharmacy reimbursement arrangements, the concessionary price setting process and the Department's capability to manage supply shortages and mitigate the impact on patients.

6.3 Secondly, the Department considers that Regulations are the most appropriate legislative vehicle to give effect to the objectives in question. The Health Service Medical Supplies (Costs) Act 2017 introduced a power to make Regulations to require the supply chain to record and provide information for specific purposes, which were to enable or facilitate:

- The remuneration/payment of NHS chemists and primary medical service providers in, or in any part of, the UK;

- The availability of products in, or in any part of, the UK and the assessment of whether the products represent value for money;

- The cost control powers in the 2006 Act.

6.4 Information related to sales/purchases, prices and costs is unlikely to be provided by all companies in the supply chain without a legislative basis. In this context, it is worth noting that the Department consulted on the draft Regulations in 2017 and took into account the views expressed by stakeholders in the final Regulations.

The Health Service Medicines (Price Control Penalties and Price Control Appeals Amendment) Regulations 2018

7. Aim and Scope of the Review

7.1 Regulation 6 of the Health Service Products (Provision and Disclosure of Information) Regulations 2018 requires the Secretary of State to carry out an annual review of the Regulations and publish a report with the conclusion of the review, which must:

1. set out the objectives intended to be achieved by the Regulations;

2. assess the extent to which these objectives are achieved; and

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

8. Overview of the regulations

8.1 The Health Service Medicines (Price Control Penalties and Price Control Appeals Amendment) Regulations 2018 apply when the Secretary of State uses powers under Section 262(1)(a) of the NHS Act 2006 to set prices of medicines.

8.2 The Regulations make a manufacturer or supplier liable to the payment of a penalty where that manufacturer or supplier charges a higher price than the limit specified by the Secretary of State.

8.3 The Regulations also amend the Health Service Medicines (Price Control Appeals) Regulations 2000 (“the Appeals Regulations”). The Appeals Regulations make provision for the appeals process where a manufacturer, supplier or where relevant, other UK producer of health service medicines or health service products has a right of appeal in relation to an enforcement decision made by the Secretary of State or any other person. The Regulations amend the Appeals Regulations to remove reference to the Council of Tribunals, which no longer exists.

9. Review methodology

9.1 No price control determinations have been made by the Secretary of State in the period April 2018 to June 2019. Therefore, the review focuses on whether the Regulations remain appropriate from a policy perspective.

10. Assessment against the policy objectives

The objectives intended to be achieved by the regulations, the extent to which they are being achieved and their continued appropriateness

10.1 The Health Service Medicines (Price Control Penalties and Price Control Appeals Amendment) Regulations 2018 entered into force on 11 April 2018. The policy objectives of the Regulations are set out in section 7 (Policy Background) of the Explanatory Memorandum which accompanied the Regulations when laid before Parliament. This section summarises each objective, assesses the extent to which each objective has been achieved and whether the objective remains appropriate.

10.2 The main objective of the Regulations was to ensure the Secretary of State can issue penalties where a manufacturer or supplier charges in excess of the limit specified in a direction made under section 262(1)(a) of the NHS Act 2006. In relation this this objective, the Regulations also specified the level of penalty and provided a right of appeal against any penalty notice issued. Separately, the Regulations updated some of the references in the Health Service Medicines (Price Control Appeals) Regulations 2000.

10.3 Under section 262(1)(a) of the NHS Act 2006 the Secretary of State can limit the price of any medicine that is not covered by the voluntary scheme for branded medicines pricing and access. The Department has publicly indicated that it intends to use this section of the NHS Act 2006 to address high-priced generics and is developing proposals for this.

10.4 Whilst no penalties have been issued by the Secretary of State, because no prices have been set, the objectives are still achieved as the Regulations ensure that when prices are set that there are robust procedures to levy penalties where manufacturers or suppliers charge above the maximum price set. The ability to issue penalties is essential for the enforcement of any direction under section 262(1)(a) that limits the price of a medicine. Therefore, the Department considers that the objectives of these Regulations are being achieved.

11. The extent to which objectives could be achieved with less regulation

11.1 As outlined above, the ability to issue penalties is essential for the enforcement of any direction under section 262(1)(a) that limits the price of a medicine. Penalties cannot be issued without the power to do so in legislation. Therefore, the Department considers that the Regulations are proportionate and that the objectives could not have been achieved with less regulation.

12. Legal Duties

12.1 A full and considered assessment of the Secretary of State's legal duties with regards to the NHS Act 2006, the Public Sector Equalities Duties and the Family Test were undertaken before the Regulations were laid. We consider that those documents set out the implications and effects of those duties and continue to be relevant to this annual review.

13. Recommendations and Conclusions

13.1 In light of the findings of these annual reviews there are currently no proposals to make changes to the Regulations.

13.2 The Department will continue to monitor the Regulations against their objectives. If changes are identified, consultation with stakeholders will take place so views can be expressed on any proposed amendments.

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