

EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (GENERAL MEDICAL SERVICES CONTRACTS) (PRESCRIPTION OF DRUGS etc.) (AMENDMENT) REGULATIONS 2018

2018 No. 1134

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 (S.I. 2005/629) (the Prescribing Regulations) set out the lists of products which either must not be ordered for patients in the provision of medical services under a general medical services contract (listed in Schedule 1 to the instrument), or may only be prescribed in specified circumstances (listed in Schedule 2). This instrument amends the Prescribing Regulations to implement changes in the prescribing of gluten free (GF) foods in primary care with effect from 4th December 2018

3. Matters of special interest to Parliament

3.1 None

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England.

4.2 The territorial application of this instrument is England.

5. European Convention on Human Rights

5.1 As the instrument is subject to the negative resolution procedure and does not amend primary legislation no statement is required.

6. Legislative Context

6.1 Part IV of the National Health Service Act 2006 (“the 2006 Act”) sets out the contractual framework under which primary medical services are provided by GPs in England. Under this framework, GPs provide services under general medical services contracts (GMS contracts) or personal medical services agreements (PMS agreements). The National Health Service (General Medical Services Contracts) Regulations 2015 (“the GMS Regulations”) set out the terms of service that apply to contractors providing primary medical services. Similar provision is made in the National Health Service (Personal Medical Services Agreements) Regulations 2015 (“the PMS Regulations”) in relation to PMS contractors. Section 88 of the 2006 Act provides that a GMS contract must contain provision requiring contractors to comply with any directions given to them by the Secretary of State in relation to the drugs, medicines or other substances that may or may not be ordered for patients in the provision of primary medical services, and requires that any directions made under this section must be given by regulations. The directions given under this section are

given in the Prescribing Regulations. The GMS and PMS Regulations require GPs to comply with the Prescribing Regulations. This instrument amends the Prescribing Regulations to restrict the prescribing of GF foods on NHS prescription to GF breads and food mixes only. Products that are banned from being prescribed are listed in Schedule 1 to the Prescribing Regulations, and there are currently a number of GF products listed in this Schedule. This instrument amends Schedule 1 to remove these GF products as the amendments will impose a generic ban on the prescribing of all foods marketed as being either gluten free or very low gluten, apart from GF breads and food mixes. Drugs, medicines and appliances that are recommended as being suitable for NHS prescribing are listed in the Drug Tariff. Implementing the proposed restrictions on GF prescribing will require the removal of a wide range of non-essential GF foods from Part XV of the Tariff to bring Part XV into line with the changes being made to the Prescribing Regulations.

7. Policy background

What is being done and why?

- 7.1 Staple GF foods have been available to patients diagnosed with gluten sensitivity enteropathies through their GPs since the 1960s. The cost of providing GF foods on NHS prescription in 2017 was £15.7m. As GF foods have become more readily available in supermarkets and other outlets, and the range of products has increased, patients are currently able to purchase these foods themselves more easily. However, patients diagnosed with gluten sensitivity enteropathies do not need to purchase alternative GF foods to enable them to eat healthily as they can safely eat meat, fish, fruit, vegetables, rice and most dairy products. In an effort to save money, many Clinical Commissioning Groups have either banned prescribing of GF foods, or have limited the types or units of GF foods that may be prescribed, by issuing prescribing guidance to GP practices in their areas. This has led to local variations in the supply of GF foods on the NHS throughout England.
- 7.2 The Department of Health and Social Care (DHSC) held a public consultation in 2017 on whether changes should be made to the prescribing of GF foods. The consultation sought responses in relation to three options: make no changes to GF prescribing in primary care, ban the prescribing of all GF foods in primary care or restrict prescribing to only certain GF foods, for example bread and mixes. The consultation received almost 8,000 responses from a range of respondents including patients, health care professionals, charities, professional bodies and pharmacists. After the responses were evaluated, the Minister decided to restrict prescribing to bread and mixes only to ensure that patients could continue to receive some essential GF foods on the NHS. This decision recognised that bread is a staple of most people's diets, and GF breads are significantly more expensive than their non-GF counterparts. GF mixes have been retained as the consultation reported that GF mixes are more useful than GF flours, and can be made into a variety of products, e.g. bread rolls, loaf of bread and various types of flat breads.
- 7.3 In certain circumstances, some foods have characteristics of drugs and are known as borderline substances. The Advisory Committee on Borderline Substances (ACBS) advises as to the circumstances in which such foods may be regarded as drugs and listed as being recommended for prescribing on the NHS in Part XV of the Drug Tariff. This list currently contains a wide range of GF foods, which in addition to breads and mixes contains many non-essential and luxury foods such as cakes and

biscuits. GPs are not restricted to only prescribing those products listed in Part XV of the Drug Tariff, and are free to prescribe other products that in their clinical judgement will benefit their patients, provided the product is not banned under the Prescribing Regulations. The policy intention therefore is to ban NHS prescribing of all products marketed as GF foods, including any similar products that may come to market in the future, apart from GF breads and GF mixes.

- 7.4 Following engagement with key stakeholders to develop the definitions of a GF bread and GF mixes, the ACBS considered applications from manufacturers of breads and mixes to have their products retained in Part XV of the Drug Tariff. This Part has been revised to remove the GF foods that will be banned from NHS prescribing when the amendments to the Prescribing Regulations come into force. This revised list in Part XV will be published in the December 2018 edition of the Drug Tariff.
- 7.5 The Amendment Regulations will ban the prescribing of all foods marketed as gluten free or very low gluten, as defined, apart from GF breads and foods mixes. The definitions of the terms ‘gluten free’ and ‘very low gluten’ are adopted from those used in EU Regulation 828/2014, which sets out the conditions under which food may be labelled as ‘gluten free’ or ‘very-low gluten’ when marketed in the EU. These definitions define the terms ‘gluten free’ and ‘very low gluten’ based on the amount of gluten they contain per kilogram of the food as sold to the final consumer, and on the ways they are prepared, produced or processed to avoid contamination by wheat, rye, barley or their crossbred varieties. The term ‘food mix’ is defined to mean a mixture of two or more ingredients which may be combined with one or more additional ingredients and baked or otherwise cooked, to avoid the prescribing of GF flour only products. Currently a number of non-essential GF products are banned by way of being listed in Schedule 1 to the Prescribing Regulations. To avoid these products being banned in two parts of the same Regulations, the Amendment Regulations amends Schedule 1 to remove the currently listed GF products.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

- 8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act

9. Consolidation

- 9.1 There are no plans to consolidate the Prescribing Regulations, but this will be kept under review.

10. Consultation outcome

- 10.1 The outcome of the consultation on the policy proposals carried out in 2017 is referred to in paragraph 7.2 above. The Department also carried out a 6-week consultation on the draft proposed Amendment Regulations from 21 August to 1 October 2018 to ensure that the definitions of banned and restricted GF foods were understood by prescribers, patients and manufacturers, that the Regulations will achieve the desired policy changes and to identify any unintended consequences that may occur from the changes as implemented by the proposed Regulations.
- 10.2 The second consultation received 932 responses from a range of respondents, including charities, health professionals, clinical commissioning groups, patients and professional associations. The responses were evaluated and are summarised as

follows: 71% of respondents agreed that the proposed Amendment Regulations were clear and would be understood by prescribers, patients and suppliers; 44% of respondents thought the changes would achieve the desired results; and 56% of respondents felt that the changes would have unintended consequences on patients, mainly due to the regional variations in prescribing policies across CCGs in England (see further in relation to this response in paragraph 11.1 below). The common themes of responses have been covered in the “Report of Responses” which will be published as the Government response, alongside an updated Impact Assessment and the Equality Impact Assessment, which is unchanged from the first consultation. The responses to this consultation have been carefully considered, and no changes to the Amendment Regulations were made as a result of the consultation.

11. Guidance

- 11.1 To address the variations in NHS supply of GF foods throughout England, NHS England will issue guidance to CCGs directing them to allow prescribing of GF foods throughout England consistently with the national arrangements set out in the Prescribing Regulations as amended. NHS Clinical Commissioners have worked closely with the Department to ensure that communications are clear and understood by prescribers, patients and clinicians. CCG guidance will be distributed to CCGs via established routes e.g. NHS Clinical Commissioners communications and the CCG bulletin. Other key stakeholders will also be made aware of the guidance in accordance with a comprehensive communications plan. A FAQs resource will be made available with the guidance.
- 11.2 The ACBS guidance on applications for GF product submissions will be updated on Gov.UK¹, following the Amendment Regulations coming into force.

12. Impact

- 12.1 The impact on business, charities or voluntary bodies is as follows. An initial Impact Assessment and an Equality Impact Assessment were prepared in relation to the proposed prescribing changes and published alongside the Report of Responses in February 2018, on the Gov.UK website². The initial Impact Assessment, which is published alongside this EM, has been updated to reflect 2017 prescription spend on GF food and revised projections for savings.
- 12.2 The changes will impact on manufacturers that supply GF foods that will no longer be supplied to patients on the NHS. Policy officials have been working closely with manufacturers to keep them up to date as the policy was being developed, and they were invited to apply for continued listing of their GF bread and mix products on the Drug Tariff for NHS prescribing. Other types of GF foods may still be supplied to pharmacies or other retailers for the patient to purchase, but will not be supplied under NHS prescriptions. We also expect that commercial supply of GF products to supermarkets and other outlets will mitigate the impact of the changes being made. With regard to the impact on charities, DHSC worked with the British Specialist Nutrition Association and Coeliac UK and kept the organisations informed of

¹ <https://www.gov.uk/government/publications/how-to-submit-an-application-for-acbs-approval/the-advisory-committee-for-borderline-substances-how-to-submit-an-application>

² <https://www.gov.uk/government/consultations/availability-of-gluten-free-foods-on-nhs-prescription>

progress to help them prepare for changes and minimise the impact on their patients and/or manufacturers. Both organisations provided good intelligence to inform the work.

- 12.3 The Drug Tariff will be updated for the December edition to ensure prescribers can access an up-to-date list of GF items that will continue to be recommended for NHS prescribing. The changes being made by the Amendment Regulations do not apply to secondary care settings as they affect primary care prescribing only.
- 12.4 There is no impact on the public sector.
- 12.5 The updated Impact Assessment is submitted with this memorandum and will be published alongside the Explanatory Memorandum on the legislation.gov.uk website.

13. Regulating small business

- 13.1 The legislation does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

- 14.1 The Department will keep the implementation of this policy under review in liaison with NHS England and other relevant stakeholders.
- 14.2 The Amendment Regulations do not include a statutory review clause.

15. Contact

- 15.1 Carol Walker at the Department of Health and Social Care, telephone: 0113 2546384 or email: carol.walker@dh.gsi.gov.uk, can be contacted with any queries regarding this instrument.
- 15.2 Carly McGurry, Deputy Director for Medicines Regulation and Prescribing Team, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Lord O'Shaughnessy at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.