



Responses to the consultation on the gluten-free food regulations

Public Consultation on the NHS (General Medical Services Contracts) (Prescription of Drugs etc) (Amendment) Regulations 2018

November 2018

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Executive Summary

In August 2018, the Department of Health and Social Care (DHSC) launched a public consultation seeking views on proposed changes to the National Health Service (General Medical Services Contracts)(Prescription of Drugs etc.) (Amendment) Regulations 2018 for the prescribing of gluten-free (GF) foods, in England. The proposed regulations would allow for GF bread and mixes only to be prescribed at NHS expense in primary care, in England.

Our consultation ran from 21st August 2018 and closed at midnight on 1st October. We received 932 responses from a range of stakeholders including patients, members of the public, health professionals, national charities and NHS organisations. We asked respondents 3 questions:

- whether the Regulations would be understood by prescribers, patients and suppliers - **71% of respondents said 'Yes'**
- if the Regulation definitions would achieve the desired changes - **44% of respondents said 'Yes'**
- if Regulations would have any unintended consequences - **56% of respondents said 'Yes'**

In addition to this, respondents raised several key issues and questions:

Retention of bread and mixes on NHS prescription - some respondents questioned whether it was better to retain flour than mixes. DHSC has previously published evidence showing that patients find GF mixes easier to use and that they give better results for baking GF items such as bread. Additionally, respondents welcomed a variety of GF breads on prescription to allow for different individual preferences. The proposed list of GF breads that will be available on NHS prescription include a range of white, brown, high fibre and seeded loaves and includes rolls and baguettes.

Variation in NHS Clinical Commissioning Group (CCG) prescribing policy - some respondents expressed concern that prescribing variation across CCGs was significant and that it left patients subjected to a postcode lottery when accessing GF foods. The proposed regulations reduce CCG variation as they allow for **a maximum of GF bread and mixes only** to be prescribed at NHS expense.

Guidance on prescribing of GF foods - respondents asked for guidance to assist the NHS with understanding the changes the proposed regulations presented. NHS England (NHS E) will publish national guidance to CCGs later this year. This will also encourage CCGs to align their local policies with national arrangements.

Drop in patient adherence to a GF diet - some respondents felt a reduction in the range of GF products would lead to a drop in the number of patients adhering to a GF diet thereby creating long-term health complications. DHSC has examined this issue in detail. Evidence shows that adherence to a GF diet could not be isolated to any single cause. Many factors are at play including product labelling and managing social occasions such as eating out. DHSC also expects the continued provision of GF bread and mixes on the NHS to support patients to maintain a GF diet.

Other issues raised are described later in this document under 'Evaluation of Responses'.

It is proposed to lay Amendment Regulations in November with a coming in to force date of early December. It is envisaged that following the changes to the Prescribing Regulations coming into force, GF foods that do not fall into the categories of GF bread and GF mixes will no longer be available on prescription in primary care, in England.

It is expected that NHSE guidance to CCGs on the prescribing of GF foods will be published before the end of the year. DHSC will provide key stakeholders with a Frequently Asked Questions document which will address common themes and questions.

1. Introduction

- 1.1 In August 2018, the Department of Health and Social Care (DHSC) launched a public consultation seeking views on proposed changes to gluten-free (GF) Prescribing Regulations, in England. The proposed regulations would allow for GF bread and mixes only to be prescribed at NHS expense in primary care, in England.
- 1.2 This document summarises the consultation responses received, including the main issues raised, and provides details on the updates that will take place to the Drug Tariff (Part XV).
- 1.3 Our consultation ran from 21st August 2018 and closed at midnight on 1st October. We asked 3 questions:
 - whether the Regulations would be understood by prescribers, patients and suppliers
 - if the Regulation definitions would achieve the desired changes
 - if Regulations would have any unintended consequences
- 1.4 We received 932 responses from a range of respondents including charities, Clinical Commissioning Groups (CCGs), health professionals, patients and professional associations. Response rates for each question were as follows:
 - 71% of respondents said that the proposed Amendment Regulations would be understood by prescribers, patients and suppliers
 - 44% of respondents thought that the changes would achieve the desired outcome
 - 56% of respondents stated that there would be some unintended consequences because of the changes
- 1.5 The main issues raised by respondents are set out below and are examined in detail later in this report under 'Evaluation of Responses.'
 - The provision of GF bread and mixes foods on prescription
 - Clarity of definitions
 - CCGs variation in GF prescribing policy
 - Advice on coeliac disease (CD)

- Wastage
 - Unintended consequences
- 1.6 It is anticipated that the proposed changes to the Prescribing Regulations (Annex A) will come into force in December 2018. Alongside these amendments, changes will be made to the Drug Tariff Part XV (Borderline Substances) to exclude GF products in the categories of biscuits, cereals, cooking aids, grains/flours, and pasta.
- 1.7 The amendments to the Prescribing Regulations will end the prescribing of all products marketed as GF foods, in England, **other than GF breads and GF mixes**. National prescribing guidance from NHSE will be issued to NHS CCGs to provide clarity on the definitions of the terms 'Gluten Free, Very Low Gluten and 'what is a gluten free mix.'
- 1.8 Those GF products currently listed in Schedule 1 of the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2018 will be removed by the Amendment Regulations, as these products will come within the remit of the proposed changes.
- 1.9 Products which are "**gluten free and low protein**" or "**low protein**" and prescribed for phenylketonuria, are not in scope for these changes. The prescribing changes to GF food will only apply in England.

2. Awareness and Engagement Activities

- 2.1 In addition to the consultation exercise itself, DHSC policy officials wrote to numerous stakeholders including Coeliac UK (the national charity for patients with CD), the British Specialist Nutrition Association (the trade association for manufacturers of GF foods) and Medical Royal Colleges to alert them to our consultation. Additionally, NHSE 'tweeted' a link to our published consultation page on GOV.UK.
- 2.2 Such actions prompted a strong response rate. In addition to the 932 responses received, our consultation page received **5,861** visits.
- 2.3 Responses from patients were very strong. The majority of respondents were a mix of patients solely, parents or other family members of those with CD or carers for CD patients.

3. Summary of Responses

- 3.1 A total of 932 responses were received. Of these, 920 were submitted on-line; 4 via e-mail and 8 via postal response forms and/or letters.
- 3.2 The survey was designed to allow respondents to state their response as 'Yes', 'No' or 'Don't Know' and then add any explanatory narrative. A breakdown of responses for each question is provided below.

Table 1: Question 1. Do you think the definitions/descriptions of the products that will be allowed in future are clear and will be understood by prescribers, patients and suppliers?

	Yes	No	Don't Know/Not Answered	Total
Number	662	181	89	932
Percentage	71%	19%	10%	

Table 2: Question 2. Do you think the proposed Amendment Regulations, as drafted, will achieve the desired changes; to provide a staple list of GF breads and GF mixes to patients on NHS Prescription?

	Yes	No	Don't Know/Not Answered	Total
Number	413	393	126	932
Percentage	44%	42%	14%	

Table 3: Question 3. Do you think the proposed Amendment Regulations will have any unintended consequences?

	Yes	No	Don't Know/Not Answered	Total
Number	519	183	230	932
Percentage	56%	20%	25%	

3.3 Respondents were asked to select a "respondent type" from a drop-down menu which they felt closely matched their stakeholder type. The responses were collated into "respondent type" as per the tables below. If a respondent stated that they were from a GP practice or replying as a health professional then they were placed into that category, even if they replied on behalf of a CCG. A breakdown of replies to questions, by respondent type, is provided as Annex B.

Table 4: Respondent type by number and percentage.

Respondent Type	Number of Respondents	Percentage of Respondents
Charity	4	0.4%
Clinical Commissioning Group (CCG)	27	2.9%
GP Practice	10	1.1%
Health Professional	117	12.6%
Member of the Public	60	6%
Other Respondent	13	1.4%
Parent/Carer/Family Member	102	10.9%
Patient	589	63.2%
Professional Association	9	1%
Private Company/Supplier	1	0.1%

4. Evaluation of Responses

4.1 A summary of the main issues raised by respondents are detailed below.

Provision of GF bread and mixes

- 4.2 44% of respondents agreed that the Amendment Regulations would achieve the desired changes to GF prescribing, in that they will provide a supply of staple breads and mixes to patients on NHS prescription. Bread provided a good source of carbohydrate and by providing it on prescription, patients could avoid purchasing it at their own expense. Many patients found GF bread more expensive to purchase in supermarkets than its gluten counterpart.
- 4.3 Some patients questioned whether it was better to retain GF flour rather than mixes. In our March 2017 consultation, which proposed changes to the availability of GF products on prescription, evidence submitted showed that patients found GF mixes easier to use and gave better results for baking GF items such as bread. Prescribing data also showed that these were more widely prescribed to patients than flour alone.
- 4.4 Respondents stated that the quality of GF bread they received on prescription was more palatable than those GF breads available to purchase and were often fortified with additional nutrients that compensated for their restricted diet. Additionally, respondents agreed that there should remain a variety of GF breads on prescription to avoid taste fatigue, and to ensure that patients with different preferences were accommodated. The proposed list of GF bread products that will continue to be supplied under NHS prescription includes a range of white, brown, high fibre and seeded loaves and includes rolls and baguettes to address this.

Clarity of definition

- 4.5 Whilst 71% of respondents felt that the definitions of GF and very low GF foods would be understood, some respondents stated that clarification was needed on what constitutes a GF mix. Additionally, health professionals and patients requested that any guidance to prescribers should be clear and unambiguous to minimise any misunderstandings. Definitions were set out in the consultation document and the proposed Prescribing Regulations but will also be provided to CCGs in the form of national guidance from NHSE.

- 4.6 The Amendment Regulations will rely on the common meaning of the term 'bread'. This is to ensure that a wide range of breads can continue to be supplied under prescription such as various types of loaves, rolls, and flat breads.

CCG prescribing variation

- 4.7 Patients and health professionals expressed concern that prescribing variation across CCGs was significant and that CCGs would not review their position following the implementation of these Regulations. Due to their autonomous nature, CCGs, can make their own decisions and policies on what medicines and treatments should be available to meet the needs of their local population, within their resource allocation.
- 4.8 The proposed regulations reduce CCG variation as they allow for **a maximum of GF bread and mixes only** to be prescribed at NHS expense. The aforementioned guidance from NHS E will encourage CCGs to align their local policies with national arrangements.

Advice on coeliac disease

- 4.9 Dietitians and health professionals stated that some GF foods were not necessarily healthy options as they contained high levels of sugar and fat to compensate for a lack of taste. Respondents felt that it was important for coeliac patients or family members to have access to dietary advice to support adherence. The National Institute for Care and Health Excellence (NICE) provides guidelines (NG20) on recognition, assessment and management of CD and clinicians are expected to follow this guidance. Furthermore, the proposed regulations allow for GF bread products and GF mixes to remain on NHS prescription to help support adherence to a GF diet.
- 4.10 Some patients felt that the diagnosis of CD took a long time, especially in children and that some GPs did not understand the condition well enough to understand patient's dietary requirements. NICE guidelines should be followed by clinicians to ensure patients have access to advice on managing their condition, thus preventing further ill health.

Wastage

- 4.11 Pharmacists and patients stated that large orders of GF bread quantities often went to waste. This occurred due to lack of storage in the patient's home, or non-collection of the order from the pharmacy. Many prescribers follow the guidelines

produced by Coeliac UK for the number of units GF food that is required. Patients can play their part by making sure they collect the prescription items they have ordered and do not order more than they can use or store before it goes out of date.

Unintended consequences

- 4.12 The majority of respondents (56%) felt that there would be unintended consequences of implementing the Amendment Regulations.
- 4.13 Some respondents felt that a reduction in the range of GF products available on prescription would lead to a drop in the number of patients adhering to a GF diet thereby creating long-term health complications for the patient.
- 4.14 DHSC has examined the issue of adherence in detail as part of its published impact assessment. Evidence from studies on this topic concluded that adherence to a GF diet could not be isolated to any single cause. Many factors were at play including product labelling, cost and information when eating out and managing social occasions. Adherence required a range of knowledge and skills to avoid all sources of gluten. DHSC also expects the continued provision of GF bread and mixes on the NHS to support patients to maintain a GF diet.
- 4.15 Some respondents were concerned by the risk of patients requesting additional bread and mixes to compensate for those non-bread and non-mix formulated foods that were no longer available on prescription. Published prescribing data from the NHS Business Services Authority shows that this phenomena has not occurred in those areas where CCGs have already restricted prescribing to GF bread and mixes. DHSC expects the likelihood of this occurring elsewhere is very low.
- 4.16 Some respondents raised concerns about the impact of the proposed regulations on low income families and questioned whether this population would be disadvantaged. DHSC has examined this as part of its published Equalities Impact Assessment. Like other patients with CD, those in low income families can still consume foods that are naturally gluten-free such as meat, fish, rice, fruit and vegetables. Alongside this, the regulations will allow for the provision of GF bread and mixes.
- 4.17 Some respondents asked the Government to intervene in the food retail sector to cap the prices for GF foods. DHSC cannot intervene in the market in this way. Pricing is a matter for the sector based on demand and supply.

Key Stakeholder Responses

- 4.18 Key responses included those from Coeliac UK, the British Specialist Nutrition Association, NHS Clinical Commissioners (NHS CC) and the National Pharmacy Association (NPA). All posed questions about the variation in CCG prescribing policy, the clarity of definitions and guidance for the NHS. DHSC is addressing these issues as previously described.
- 4.19 NHS CC questioned the rationale for retaining GF mixes on prescription rather than flour. DHSC's response to this is explained above. Additionally, the NPA asked for further implementation time to allow services to adjust to the proposed changes. DHSC first announced its intention to restrict GF prescribing to bread and mixes in February 2018 and has since worked closely with a range of stakeholders to help prepare services and patients for change. Further communication activities are provided under 'Guidance and Communications.'

5. Guidance and Communications

- 5.1 Subject to the Amendment Regulations coming into force, prescriptions issued for the supply of GF products after 4th December 2018 will be for GF bread or GF mixes only. GP surgeries will need to update their prescribing systems to reflect these changes.
- 5.2 NHSE will publish national guidance to CCGs advising them of the updated prescribing regulations. DHSC will provide key stakeholders with a FAQ document which will address common themes and questions. This is attached as Annex C.
- 5.3 Manufacturers/suppliers of GF foods have been informed about which of their GF bread and mix products have been recommended by DHSC, and therefore retained in Part XV of the Drug Tariff. This will help enable them to manage stocks and future supplies of GF food.
- 5.4 The December edition of the Drug Tariff will reflect the proposed regulations. A copy of those bread and mixes that will be available for prescription is attached as Annex D.

6. The Public-Sector Equality Duty (PSED) and Health Duties

- 6.1 When taking decisions, public authorities are required to have due regard to the Public Sector Equality Duty (PSED), often referred to as the general equality duty. This duty was created by the Equality Act 2010 and came into force in April 2011. Under this duty, which is set out in section 149 of the Equality Act, those subject to the general equality duty must have due regard to the need to:
- Eliminate unlawful discrimination, harassment and victimisation
 - Advance equality of opportunity between different groups
 - Foster good relations between different groups
- 6.2 The duty to have due regard to the need to eliminate discrimination covers age, disability, sex, gender re-assignment, pregnancy and maternity, race, religion or belief and sexual orientation.
- 6.3 The Secretary of State for Health and Social Care has a duty under the National Health Service Act 2006 (Section 1A) to secure an improvement in the quality of services. The release of funds from any GF food prescribing will be re-deployed into other parts of the system. The Secretary of State also has a duty under Section 1C to have regard as to reducing inequalities.
- 6.4 As part of its March 2017 consultation 'Availability of gluten-free foods on NHS prescription', DHSC published an Equality Impact Assessment. This provides information about the equality issues and the analysis of the information received as part of the consultation. Issues include the impact of changes on low income families, vulnerable patients such as children and those with mobility issues.

7. Next Steps and Timings

- 7.1 It is proposed to lay Amendment Regulations in November with a coming in to force date of early December.
- 7.2 The revised list of Gluten Free foods that will be available on NHS prescription will be supplied to the NHS Business Services Authority (BSA) who update the Drug Tariff on behalf of DHSC.
- 7.3 It is envisaged that following the changes to the Prescribing Regulations coming into force, GF foods that do not fall into the categories of GF bread and GF mixes will no longer be available on prescription in primary care in England.
- 7.4 It is expected that NHS England guidance to CCGs on the prescribing of GF foods will be published before the end of the year.

Annex A - Prescribing Regulations

National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2018

The Secretary of State for Health and Social Care makes the following Regulations in exercise of the powers conferred by sections 88 and 272(7) and (8) of the National Health Service Act 2006ⁱ:

Citation and commencement

1. These Regulations may be cited as the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2018 and come into force [day] [month] 2018.

Amendment of the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004

2. The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004ⁱⁱ are amended as follows.

(2) For regulation 2 substitute—

"Drugs, medicines and other substances that may not be ordered.

"2.—(1) The following drugs, medicines and other substances may not be ordered for patients in the provision of medical services under a general medical services contract—

- (a) a drug, medicine or other substance which is listed in Schedule 1,
- (b) any food marketed in England as gluten-free food, or
- (c) any food marketed in England as very low gluten food.

(2) But—

- (a) paragraph (1)(b) does not apply to gluten-free bread or a gluten-free food mix;
- (b) paragraph (1)(c) does not apply to very low gluten bread or a very low gluten food mix.

(3) For the purposes of this regulation—

- (a) a food is gluten-free if the food, as sold to the final consumer -
 - (i) contains no more than 20mg/kg of gluten; and

- (ii) where it contains oats has been specially produced, prepared and or processed in a way to avoid contamination by wheat, rye, barley, or their crossbred varieties:

(b) a food is very low gluten if the food as sold to the final consumer, contains no more than 100mg/kg of gluten and consists of, or contains, one or more ingredients made from wheat, rye, barley, oats or their cross bred varieties which have been specially processed to reduce the gluten content, and where it contains oats —

(i) it has been specially produced, prepared and or processed in a way to avoid contamination by wheat, rye, barley, or their cross bred varieties, and

(ii) the gluten content of the oats does not exceed 20mg/kg

(4) In this regulation—

“food mix” means a mixture of two or more ingredients which is to be—

(a) combined with any one or more additional ingredients, and

(b) baked or otherwise cooked;

“gluten” means a protein fraction from wheat, rye, barley, oats or their crossbred varieties and derivatives, which is insoluble in water and 0.5 M sodium chloride solution.”

(3) In Schedule 1 (drugs, medicines and other substances not to be ordered under a general medical services contract) omit the following entries for —

Appleford’s Gluten-Free Rice Cakes;

Clara’s Kitchen Glute-Free Porridge;

Ener-G Gluten-free and Soya-free Macaroon Cookies;

Ener-G Gluten-free Rice Peanut-Butter Cookies;

Ener-G Gluten-free Rice Walnut Cookies;

Glutafin Gluten-Free Chocolate Chip Cookies;

Glutafin Gluten-Free Custard Cream Biscuits;

Glutafin Gluten-Free Gingernut Cookies;

Glutafin Gluten-Free Milk Chocolate Biscuits;

Glutafin Gluten-Free Milk Chocolate Digestive Biscuits;

Glutafin Gluten-Free Shortcake Biscuits;

Glutano Gluten-Free Chocolate Hazelnut Wafer Bar;

Glutano Gluten-Free Muesli;

Glutano Gluten-Free Pretzel;

Glutano Gluten-Free Wafer;

Glutano Gluten-Free Wafer, Cream Filled;

Gratis Gluten-Free Tricolour Pasta;
Juvela Gluten-Free Mince Pies;
Juvela Gluten-Free Sage & Onion Stuffing;
Rite-Diet Gluten-Free Baking Powder;
Rite-Diet Gluten-Free Banana Cake;
Rite-Diet Gluten-Free Bourbon Biscuits;
Rite-Diet Gluten-Free Christmas Pudding;
Rite-Diet Gluten-Free Coconut Cookies;
Rite-Diet Gluten-Free Date & Walnut Cake;
Rite-Diet Gluten-Free Gingernut Cookies;
Rite-Diet Gluten-Free Half Covered Chocolate Digestive Biscuits;
Rite-Diet Gluten-Free Lemon Madeira Cake;
Rite-Diet Gluten-Free Muesli Cookies;
Rite-Diet Gluten-Free Rich Fruit Cake;
Rite-Diet Gluten-Free Wheat-Free Mince Pies;
Schar Gluten Free Sponge Cake;
Sunnyvale Gluten-Free Rich Plum Pudding;
Sun Yums Gluten Free & Dairy Free Almond and Coconut Cake;
Sun Yums Gluten Free & Dairy Free Banana and Sesame Cake;
Sun Yums Gluten Free & Dairy Free Carob and Mint Cake;
Sun Yums Gluten Free & Dairy Free Ginger and Pecan Nut Cake;
Sun Yums Gluten Free & Dairy Free Jaffa Spice Cake;

Signed by authority of the Secretary of State for Health and Social Care

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 (S.I. 2004/629) ("the 2004 Regulations") to restrict the circumstances in which products marketed in England as gluten-free foods and very low gluten foods may be ordered on NHS prescription by prescribers of primary medical services providers (which are generally GP practices).

Regulation 2 of the 2004 Regulations is substituted by Regulation 2(2) of these Regulations. As substituted, regulation 2 of the 2004 Regulations:

amended so that gluten-free and very low gluten foods can no longer generally be ordered on prescription. However, exceptions to this general rule are made for:

- provides that products marketed as gluten-free and very low gluten foods can no longer generally be ordered on NHS prescription with exceptions for gluten-free bread and mixes, and for very low gluten bread and food mixes (paragraphs (1) and (2))
- defines a food as "gluten-free" or as "very low gluten" by reference to its ingredients and its gluten content is measured in milligrams per kilogram (paragraph (3))
- defines other terms used in the regulation (paragraph (4)).

Schedule 1 to the 2004 Regulations is amended to remove entries relating to gluten-free foods as a result of the substituted regulation 2 (regulation 2(3) of these Regulations).

Annex B - Breakdown by Respondent Type

Respondents were asked to select a "respondent type" from a drop-down menu which they felt closely matched their organisational or individual type. The classification selected by the respondent has been used for the tables below.

Charity

4 responses

	Q1. Do you think the definitions/descriptions of the products that will be allowed in future are clear and will be understood by prescribers, patients and suppliers?	Q2. Do you think that the proposed Amendment Regulations as drafted, will achieve the desired changes; to provide a staple list of GF bread and GF mixes to patients on NHS prescription?	Q3. Do you think the proposed Amendment Regulations will have any unintended consequences?
Yes	4 (100%)	2 (50%)	3 (75%)
No	0	1 (25%)	0
Don't Know/Not Answered	0	1 (25%)	1 (25%)

Clinical Commissioning Groups (CCGs)

27 responses

	Q1. Do you think the definitions/descriptions of the products that will be allowed in future are clear and will be understood by prescribers, patients and suppliers?	Q2. Do you think that the proposed Amendment Regulations as drafted, will achieve the desired changes; to provide a staple list of GF bread and GF mixes to patients on NHS prescription?	Q3. Do you think the proposed Amendment Regulations will have any unintended consequences?
Yes	21 (78%)	19 (70%)	10 (37%)
No	5 (19%)	5 (19%)	11 (41%)
Don't Know/Not Answered	1 (4%)	3 (11%)	6 (22%)

GP Practices

10 responses

	Q1. Do you think the definitions/descriptions of the products that will be allowed in future are clear and will be understood by prescribers, patients and suppliers?	Q2. Do you think that the proposed Amendment Regulations as drafted, will achieve the desired changes; to provide a staple list of GF bread and GF mixes to patients on NHS prescription?	Q3. Do you think the proposed Amendment Regulations will have any unintended consequences?
Yes	9 (90%)	7 (70%)	4 (40%)
No	1 (10%)	2 (20%)	5 (50%)
Don't Know/Not Answered	0	1 (10%)	1 (10%)

Health Professionals

117 responses from; other approved prescribers, dietitians, registered nutritionists, nurses, pharmacists, scientists, pharmacy technicians, practice managers, and primary care pharmacists.

	Q1. Do you think the definitions/descriptions of the products that will be allowed in future are clear and will be understood by prescribers, patients and suppliers?	Q2. Do you think that the proposed Amendment Regulations as drafted, will achieve the desired changes; to provide a staple list of GF bread and GF mixes to patients on NHS prescription?	Q3. Do you think the proposed Amendment Regulations will have any unintended consequences?
Yes	77 (66%)	81 (69%)	56 (48%)
No	28 (24%)	21 (18%)	44 (38%)
Don't Know/Not Answered	12 (10%)	15 (13%)	17 (15%)

Members of the public

60 responses

	Q1. Do you think the definitions/descriptions of the products that will be allowed in future are clear and will be understood by prescribers, patients and suppliers?	Q2. Do you think that the proposed Amendment Regulations as drafted, will achieve the desired changes; to provide a staple list of GF bread and GF mixes to patients on NHS prescription?	Q3. Do you think the proposed Amendment Regulations will have any unintended consequences?
Yes	40 (67%)	32 (53%)	23 (38%)
No	16 (27%)	23 (38%)	22 (37%)
Don't Know/Not Answered	4 (7%)	5 (8%)	15 (25%)

Other respondents

13 responses

	Q1. Do you think the definitions/descriptions of the products that will be allowed in future are clear and will be understood by prescribers, patients and suppliers?	Q2. Do you think that the proposed Amendment Regulations as drafted, will achieve the desired changes; to provide a staple list of GF bread and GF mixes to patients on NHS prescription?	Q3. Do you think the proposed Amendment Regulations will have any unintended consequences?
Yes	6 (46%)	2 (15%)	4 (31%)
No	2 (15%)	6 (46%)	1 (8%)
Don't Know/Not Answered	5 (38%)	5 (38%)	8 (62%)

Parents, Carers and Family Members

102 responses

	Q1. Do you think the definitions/descriptions of the products that will be allowed in future are clear and will be understood by prescribers, patients and suppliers?	Q2. Do you think that the proposed Amendment Regulations as drafted, will achieve the desired changes; to provide a staple list of GF bread and GF mixes to patients on NHS prescription?	Q3. Do you think the proposed Amendment Regulations will have any unintended consequences?
Yes	67 (66%)	30 (29%)	70 (69%)
No	20 (20%)	63 (62%)	10 (10%)
Don't Know/Not Answered	15 (15%)	9 (9%)	22 (22%)

Patients

589 responses

	Q1. Do you think the definitions/descriptions of the products that will be allowed in future are clear and will be understood by prescribers, patients and suppliers?	Q2. Do you think that the proposed Amendment Regulations as drafted, will achieve the desired changes; to provide a staple list of GF bread and GF mixes to patients on NHS prescription?	Q3. Do you think the proposed Amendment Regulations will have any unintended consequences?
Yes	432 (73%)	234 (40%)	344 (58%)
No	106 (18%)	269 (46%)	89 (15%)
Don't Know/Not Answered	51 (9%)	86 (15%)	156 (26%)

Professional Associations and Royal Colleges

9 responses

	Q1. Do you think the definitions/descriptions of the products that will be allowed in future are clear and will be understood by prescribers, patients and suppliers?	Q2. Do you think that the proposed Amendment Regulations as drafted, will achieve the desired changes; to provide a staple list of GF bread and GF mixes to patients on NHS prescription?	Q3. Do you think the proposed Amendment Regulations will have any unintended consequences?
Yes	6 (67%)	6 (67%)	4 (44%)
No	2 (22%)	2 (11%)	1 (11%)
Don't Know/Not Answered	1 (11%)	1 (11%)	4 (44%)

Private Company and Suppliers

1 response

	Q1. Do you think the definitions/descriptions of the products that will be allowed in future are clear and will be understood by prescribers, patients and suppliers?	Q2. Do you think that the proposed Amendment Regulations as drafted, will achieve the desired changes; to provide a staple list of GF bread and GF mixes to patients on NHS prescription?	Q3. Do you think the proposed Amendment Regulations will have any unintended consequences?
Yes	0	0	1 (100%)
No	1 (100%)	1 (100%)	0
Don't Know/Not Answered	0	0	0

Annex C - Frequently Asked Questions

What is coeliac disease?

Coeliac disease (CD) is a serious medical condition where the body's immune system attacks its own tissue when gluten is eaten.

Is there any cure?

The only medical treatment for CD is strict adherence to a gluten-free (GF) diet for life. Gluten is not necessary for a healthy diet and patients can safely exclude it from their diet and still eat healthily without purchasing formulated foods. Naturally GF foods include meat, fish, vegetables, fruit, rice and most dairy products.

In practice, patients usually adhere to a GF diet through some combination of naturally GF food and formulated GF food both purchased privately and obtained through prescription.

What are the implications of not following a GF diet?

Non-adherence to GF diets can cause serious health problems. According to NICE, those who are not following a strict GF diet are at a higher risk of long term complications, including osteoporosis, ulcerative jejunitis, intestinal malignancy, functional hyposplenism, vitamin D deficiency and iron deficiency. Other guidance, that of the British Society of Gastroenterology, identifies CD patients as being at increased risk of osteoporosis and bone fracture.

Why are GF foods available on the NHS?

GF foods are available on prescription to patients diagnosed with gluten sensitivity enteropathies, including CD. The original policy aim of prescribing GF foods was to encourage patients to adhere to a GF diet, when availability of formulated GF foods was limited. This helped prevent more complex health problems from developing.

Why does the Government want to make changes to the availability of GF foods?

As formulated GF foods (and naturally GF foods including meat, fish, vegetables, fruit, rice and most dairy products) are now available to purchase in supermarkets and other outlets, the policy objective is to make cost savings through restricting the prescribing of GF foods, whilst maintaining adherence among patients and so avoiding detrimental health effects.

How much does the NHS spend on the prescribing of GF foods?

Data from 2017 shows that nationally the NHS spent £15.7 million on the basic cost of GF foods. This mainly related to the prescribing of staple foods such as bread, flour and mixes but also to non-staple items including cakes, pastries and cereals which were all prescribed at NHS expense.

What options for change has the Government considered?

In March 2017, the Department of Health & Social Care (DHSC) published the consultation 'Availability of gluten-free foods on prescription.' This presented respondents with 3 options for change:

Option 1: Make no changes to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004. Under this option GF foods would continue to be prescribed in primary care at NHS expense.

Option 2: To add all GF foods to Schedule 1 of the above regulations to end the prescribing of GF foods in primary care. Under this option no GF foods would be available on prescription in primary care.

Option 3: To only allow the prescribing of certain GF foods (e.g. bread and mixes) in primary care, by amending Schedule 1 of the above regulations.

The consultation was published on GOV.UK and is available at the link, below.

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

How many responses did the consultation receive?

DHSC received almost 8,000 responses. These came from a wide range of stakeholders including patients, health care professionals, manufacturers of GF foods, charities and NHS organisations.

What option did the Government decide upon?

The Government decided on option 3 which restricts GF prescriptions to certain bread and mixes. This delivers savings to the NHS and helps mitigate the risk that those on lower incomes would not be able to purchase their own GF foods from retail outlets where price is often higher and availability more limited. The majority of respondents preferred this option. Changes made will apply to primary care prescribing and will not impact secondary care settings.

What happened after the 2017 consultation?

In August 2018, DHSC carried out a second consultation which shared a draft copy of the revised regulations and invited scrutiny of these to ensure they would work in practice. The consultation received over 900 responses from a range of stakeholders including patients and carers of patients, members of the public, dietitians, pharmacists and NHS Clinical Commissioning Groups (CCGs). The majority of respondents agreed that the revised regulations would be understood by the service and would provide a staple list of gluten-free bread and mix products. At time of writing, DHSC expects the revised regulation to come in to force in December.

The consultation was published on GOV.UK and is available at the link, below.

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

What will the revised regulations mean in practice?

The GF food list as published in Part XV of the Drug Tariff will be smaller and mean that patients with established gluten sensitive enteropathies will retain access to GF bread and mixes on NHS prescription.

GF products that fall outside the category of a bread or a mix will no longer be prescribed at NHS expense. Prescribing regulations will be amended to reflect these changes.

What GF foods do CCGs currently allow on prescription?

Categories of GF foods listed in the Drug Tariff include bread, pasta, flour, grains, biscuits, mixes, cereals and pizza bases.

Availability of GF foods on NHS prescription varies according to local CCG policy. Some follow guidelines that are provided by the charity for patients with coeliac disease, Coeliac UK, whilst others have restricted prescribing to certain products and/or patient groups, or have restricted GF products all together. The new regulations are intended to reduce variation.

Will all CCGs prescribe bread and mixes?

The amended regulations are intended to reduce the variation in the provision of GF foods on prescription. All GF food, other than bread and mixes, will be included in Schedule 1 of the "National Health Services (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004. CCGs are encouraged to align their local policies with the amended regulations.

Will CCGs be provided with guidance to support their prescribing policies?

We expect NHS England to publish national guidance to CCGs later this year. This will encourage CCGs to align their local policies with national arrangements.

How can a manufacturer apply to have a new GF product listed in the Drug Tariff for prescribing in England?

In the interim period before the revised regulations come in to force, manufacturers should apply to the ACBS in the usual way and the product will be assessed using the existing criteria. Details of how to do this are available at:

<https://www.gov.uk/government/groups/advisory-committee-on-borderline-substances>

Once the prescribing changes come into force, only applications for GF foods in the categories of bread and mixes will be considered by the ACBS.

Some patients who have purchased a pre-payment certificate to cover the cost of their GF prescriptions will now only be able to access a limited range of products. Will they be able to obtain a refund?

There cannot be a refund on a partly used pre-paid certificate in light of the amended prescribing regulations of GF foods. Changes to GF prescribing were announced in February 2018 giving patients and NHS services an extended period of notice before the amended regulations come into force in December 2018.

Patients can only claim a refund of a prescription prepayment certificate if they become entitled to free NHS prescriptions. More information is available at the following website:

<https://www.nhsbsa.nhs.uk/help-nhs-prescription-costs/free-nhs-prescriptions>

Pre-payment certificates cover all prescription medicines and not just GF food so can continue to be used until they expire.

When will the Drug Tariff be updated with the revised regulations?

We expect the December edition of the Drug Tariff to reflect the new position.

When do the amended regulations come in to force?

We expect the amended regulations to come into force in December 2018.

Annex D - Revised GF Product List

Product Name
Barkat gluten-free all purpose flour mix
Barkat gluten-free brown rice bread
Barkat gluten-free hi-fibre bread mix
Barkat gluten-free par-baked baguettes
Barkat gluten-free par-baked rolls
Barkat gluten-free par-baked white bread sliced
Barkat gluten-free wheat free multigrain rice bread
Barkat gluten-free white rice bread
Barkat gluten-free wholemeal sliced bread
Ener-G gluten-free brown rice bread
Ener-G gluten-free dinner rolls
Ener-G gluten-free rice loaf
Ener-G gluten-free Seattle brown loaf
Ener-G gluten-free tapioca bread
Ener-G gluten-free white rice bread
Finax gluten-free coarse flour mix
Finax gluten-free fibre bread mix
Finax gluten-free flour mix
Genius gluten-free brown sandwich bread sliced
Genius gluten-free seeded brown farmhouse loaf sliced
Genius gluten-free white sandwich bread sliced
Glutafin gluten-free 4 white rolls
Glutafin gluten-free baguettes
Glutafin gluten-free bread mix

Glutafin gluten-free fibre bread mix
Glutafin gluten-free fibre loaf sliced
Glutafin gluten-free high fibre loaf sliced
Glutafin gluten-free multipurpose white mix
Glutafin gluten-free part-baked 2 long white rolls
Glutafin gluten-free part-baked 4 fibre rolls
Glutafin gluten-free part-baked 4 white rolls
Glutafin gluten-free Select bread mix
Glutafin gluten-free Select fibre bread mix
Glutafin gluten-free Select fibre loaf sliced
Glutafin gluten-free Select fresh brown loaf sliced
Glutafin gluten-free Select fresh seeded loaf sliced
Glutafin gluten-free Select fresh white loaf sliced
Glutafin gluten-free Select multipurpose fibre mix
Glutafin gluten-free Select multipurpose white mix
Glutafin gluten-free Select seeded loaf sliced
Glutafin gluten-free Select white loaf sliced
Glutafin gluten-free wheat-free fibre mix
Glutafin gluten-free white loaf sliced
Glutenex gluten-free white bread mix
Innovative Solutions gluten-free bakery blend
Just: gluten-free good white bread sliced
Just: gluten-free good white rolls
Just: gluten-free white sandwich bread
Juvela gluten-free bread rolls
Juvela gluten-free fibre bread rolls
Juvela gluten-free fibre loaf sliced

Juvela gluten-free fibre loaf unsliced
Juvela gluten-free fibre mix
Juvela gluten-free fresh fibre loaf sliced
Juvela gluten-free fresh fibre rolls
Juvela gluten-free fresh white loaf sliced
Juvela gluten-free fresh white rolls
Juvela gluten-free harvest mix
Juvela gluten-free loaf sliced
Juvela gluten-free loaf unsliced
Juvela gluten-free mix
Juvela gluten-free part-baked fibre bread rolls
Juvela gluten-free part-baked fibre loaf
Juvela gluten-free part-baked loaf
Juvela gluten-free part-baked white bread rolls
Lifestyle gluten-free brown bread
Lifestyle gluten-free brown bread rolls
Lifestyle gluten-free high fibre bread rolls
Lifestyle gluten-free white bread rolls
Mums Mill gluten-free quick bread mix
Orgran gluten-free bread mix
Proceli basic mix
Proceli gluten free part-baked baguettes
Tobia Brown Teff Bread Mix
Tobia White Teff Bread Mix
Tritamyl gluten-free brown bread mix
Tritamyl gluten-free flour mix
Tritamyl gluten-free white bread mix

Warburtons gluten free brown bread sliced
Warburtons gluten free brown rolls
Warburtons gluten free white bread sliced
Warburtons gluten free white rolls

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OGL

ⁱ 2006 c.41

ⁱⁱ S.I. 2004/629