



Department
of Health &
Social Care

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

- Gluten Free Food on NHS Prescription in England

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Executive summary

The Department of Health and Social Care (DHSC) launched a public consultation to seek views on whether to make any changes to the availability of gluten free (GF) foods that can be prescribed in primary care in England.

The consultation sought views on three options:

- Option 1: Make no changes to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 (the Prescribing Regulations).
- Option 2: To ban GF prescribing of all GF foods in primary care by amending the above Regulations.
- Option 3: To only allow the prescribing of certain GF foods (e.g. bread and flour) in primary care, by amending the above Regulations.

The Report of Responses was published on 1st February 2018 and provided information about the consultation responses. Alongside this, an updated impact assessment and an equalities impact assessment was published.

The Health and Social Care Minister's preferred option is Option 3; that is to allow the prescribing of certain types of GF foods (e.g. bread and mixes) in primary care. It is proposed to implement these changes by laying the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2018 (the Amending Regulations) to amend the Prescribing Regulations, and by way of updating Part XV and Part XVIII A of the Drug Tariff in line with these changes.

The proposed changes to the Prescribing Regulations and the Drug Tariff will result in only GF breads and GF mixes being available on prescription in primary care, as the preferred product types following the consultation. A Task and Finish Group was formed from a range of key stakeholders, including Coeliac UK, the British Dietetic Association (BDA), the British Specialist Nutrition Association (BSNA), and Clinical Commissioners. This group developed the process used to establish which products will remain in the Drug Tariff, taking into account patient need for a variety of staple GF foods in the bread and mix categories.

The Advisory Committee on Borderline Substances (ACBS) considered requests from GF manufacturers/suppliers on GF bread or GF mix products in relation to the products they wanted to retain in the Drug Tariff; these continued listings were recommended on the basis of patient need and the Minister's decision to restrict available food types to bread and mixes.

The appended draft Amendment Regulations are now subject to consultation to ensure they are clear and reflect the Health Minister's preferred option. These Regulations will only apply in England.

1. Introduction

- 1.1. The Department of Health and Social Care (DHSC) held a public consultation which sought views on whether any changes should be made to prescribing legislation for Gluten Free (GF) foods. A range of options were set out in the consultation document, which included ending the prescribing of GF foods by adding them to Schedule 1 to the Prescribing Regulations, or restricting their availability by way of amending Schedule 2 to these Regulations. Schedule 1 is commonly known as the blacklist, and GPs are not permitted to prescribe products from this list at NHS expense.
- 1.2. This document forms the consultation on the proposed legislative changes to the Prescribing Regulations, Part XV and Part XVIII A of the Drug Tariff.
- 1.3. A total of 7,941 responses were received to the earlier consultation and those came from a variety of respondents including, charities, Clinical Commissioning Groups (CCGs), health professionals, patients and professional associations.
- 1.4. The responses were evaluated and published in the "Report of Responses" document, which detailed the findings, and presented the main issues raised, including points of agreement. Many CCGs have made changes to local prescribing formularies and have restricted or ended the supply of GF food¹ on prescription. It is anticipated that the proposed changes to the Prescribing Regulations 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.
- 1.5. The proposed amendments to the Prescribing Regulations will end the prescribing of all GF foods other than GF breads and GF mix items in England. They will provide clarity on the definitions of: Gluten Free, Very Low Gluten, and what is considered to be a gluten free mix for the purposes of prescribing.
 - 1.5.1. A food is **gluten-free** if the food, as sold to the final consumer, contains no more than 20mg/kg of gluten; and 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.
 - 1.5.2. A food is **very low gluten** if the food—
 - (i) consists of, or contains, one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been specially processed to reduce the gluten content, and
 - (ii) as sold to the final consumer, contains no more than 100mg/kg of gluten.
 - 1.5.3. A "**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;
 - 1.5.4. "**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. A food is gluten free if the food as sold to the final consumer, contains no more than 20mg/kg of gluten, and 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.

- 1.6. As the proposed changes will end the NHS prescribing of all GF foods other than bread and mixes, the range of GF products that are currently banned by way of being listed in Schedule 1 will be removed by the Amendment Regulations, as these products will come within the ambit of the proposed changes. It is important to note that products which are "gluten free and low protein" will not be in scope for these changes, and that these Regulations apply in England only.

2. Implementation Plan

- 2.1. The Minister's preferred option is to retain a range of bread and mix products on NHS prescription. Feedback from the consultation exercise was that GF bread forms a staple part of the diet and that it remains an expensive product for patients to buy when compared to a standard loaf of bread. Respondents stated that it was important to retain "mixes" instead of GF flour, because the mixes are a more versatile product which can be used to make a variety of food items, such as a loaf of bread, individual bread rolls, a pizza base etc. They also stated that GF flour on its own was often difficult to bake with.
- 2.2. It is proposed that several areas of work will be undertaken to implement changes to GF prescribing. These changes are described in this chapter and will be introduced in a staged approach, allowing patients, clinicians and manufacturers a period of time to adjust.

Mechanisms for Change

- 2.3. It is proposed that several areas of work will be undertaken to implement the ministerial decision:
 - Secondary legislation to ensure that products that will no longer be provided are "blacklisted"
 - An updated list of GF bread and GF mixes in Part XV of the Drug Tariff
- 2.4. The current GF food list contains items that will no longer be prescribed and a large number of bread types and mixes. As of January 2018 there were 95 bread products included in the Advisory Committee on Borderline Substances (ACBS) recommended list (replicated in Part XV of the Drug Tariff). These products include; loaves of white and brown bread, sliced and unsliced bread, fibre loaf, seeded loaf, bread rolls, baguettes, part baked rolls, and pizza bases.
- 2.5. It is proposed to update the list of GF bread and mixes in Part XV of the Drug Tariff. Suppliers/manufacturers were invited to apply for the products they wished to be retained, via an abridged ACBS process, these products have been reviewed by the ACBS to ensure they meet the above definitions and remain available for patients. The proposed changes to GF food prescribing (by category) is summarised in Table 1. It is not proposed to exclude GF foods from prescribing by category as these would need clear definitions and could lead to confusion for prescribers, patients and manufacturers. A range of GF bread and GF mixes will be retained to allow patient choice.

Legislation

- 2.6. The first change will be to amend Part XV of the Drug Tariff to remove the products which are discontinued, or withdrawn by suppliers/manufacturers. The list will reflect a range of GF bread and GF mixes. The Prescribing Regulations will be amended to provide that all GF foods other than GF breads and mixes cannot be prescribed on the NHS.
- 2.7. The next step will be to make and formally lay the finalised Amendment Regulations before Parliament. Once the Amendment Regulations come into force Schedule 1 will be amended to remove previously listed GF products. Schedule 1 to the Prescribing

Regulations contains a list of individually named products that cannot be prescribed on the NHS. It is an historic list and has not been updated since approximately 1984. The list of products is replicated in Part XVIII A of the Drug Tariff and includes some GF foods which are listed by name. The proposed amendments to exclude all GF food, with the exception of GF bread and GF mixes will mean that GF food items that can no longer be prescribed will not have to be individually named in Schedule 1 or Part XVIII A of the Drug Tariff.

Table 1 - Gluten Free Food Product Categories

Food Type/Category	Drug Tariff <i>ii</i> – Number of Item Types	Implementation
GF, GF & Wheat Free (WF) Biscuits (includes crispbreads and crackers)	25 products	Will no longer be available. All items to be removed from the Drug Tariff (Part XV).
GF, GF&WF Bread (includes rolls, part baked bread, and pizza bases)	95 products	To retain provision; ACBS review of GF bread against agreed definition.
GF, GF&WF Cakes/Pastries	No ACBS approved products	Will not be available.
GF WF Cereals	9 products	Will no longer be available. All items to be removed from the Drug Tariff (Part XV).
GF WF Cooking Aids	2 products	Will no longer be available. All items to be removed from the Drug Tariff (Part XV).
GF, GF&WF Grains/Flours	12 products	Will no longer be available. All items to be removed from the Drug Tariff (Part XV).
GF, GF&WF Mixes	29 products	To retain provision; ACBS review of GF mixes against agreed definition.
GF, GF&WF Pasta (includes fusilli, lasagne, macaroni and spaghetti)	23 products	Will no longer be available. All items to be removed from the Drug Tariff (Part XV).
GF, GF&WF Ready meals	No ACBS approved products	Will not be available.

- 2.8. Policy officials will work with key stakeholders, including the ACBS, Coeliac UK and manufacturers' representatives on strategies to update the list of GF bread and GF mixes that can be provided at NHS expense. The overall aim and objective is to ensure

Implementation Plan

patients retain an element of choice within the range of GF breads and mixes, and that this will be at a reasonable cost to the NHS. The GF food list will be smaller and allow patients with established gluten sensitive enteropathies to retain access to basic GF foods on NHS prescription. The GF food list will continue to be published in Part XV of the Drug Tariff.

3. Stakeholder Engagement and Consultation Questions

- 3.1. Stakeholders are invited to consider the draft proposed Amendment Regulations appended to this consultation document and respond to the questions below to ensure that the proposed legislative changes are meaningful, fair and inclusive.

Questions

- 3.2. 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
- 3.3. Do you think that 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
- 3.4. Do you think the proposed Amendment Regulations will have any unintended consequences?
Yes/No/Don't know

4. Guidance and Communications

- 4.1. Subject to the Prescribing Regulations coming into force, prescriptions issued after December 2018 will only be for GF bread or GF mixes.
- 4.2. GP surgeries will need to update their prescribing systems to reflect the proposed changes to GF prescribing.
- 4.3. Subject to any comments received in relation to the proposed changes in the Prescribing Regulations, it is expected that NHS England will issue guidance to CCGs urging them to comply with the national arrangements for GF prescribing. Information will be provided through a range of communications to patients, prescribers, pharmacists, dieticians, and commissioners to ensure they are aware of the changes and the impact on them. A Frequently Asked Questions (FAQ) will be made available which will address common themes and questions.
- 4.4. Manufacturers/suppliers of GF foods have been informed about which GF bread and mixes have been recommended by the ACBS, 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. Next Steps and Timings

- 5.1. Policy officials will engage with key stakeholders to ensure that the range of products that remain in Part XV of the Drug Tariff will provide patients with staple provisions to support adherence to a GF diet, at a reasonable cost to the NHS.
- 5.2. Engagement is on-going with the three devolved administrations (Wales, Scotland and Northern Ireland) regarding arrangements for ACBS recommended GF foods that, subject to the proposed Amendment Regulations, will no longer be available in England. The Drug Tariff publication applies to England and Wales, so arrangements will be made to clarify which GF foods are available in both nations following regulation changes.

Timings

- 5.3. A specially convened meeting of the ACBS to consider GF products in the bread and mixes categories took place on 11 June 2018, and outcomes were notified to manufacturers/suppliers.
- 5.4. The implementation of the Amendment Regulations is expected to be in December 2018, alongside the proposed amendments to the November 2018 Drug Tariff. Subject to the outcome of the consultation, 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.

6. How to Respond to the Consultation

Responding to the consultation

The Department welcomes responses to all of the questions above. Please submit your responses to the questions by 23:59 hours on Monday 1st October 2018.

The preferred method of receiving your response is via the on-line consultation questionnaire, which can be found alongside this consultation document on the Department's website:

<https://www.gov.uk/government/organisations/department-of-health-and-social-care>

Please use this to record your responses. Alternatively, a paper copy of the response form is available on request using the email address below:

GFprescribing@dh.gsi.gov.uk

If you do not have internet or e-mail access, then please write to:

Medicines Regulations & Prescribing
Department of Health and Social Care
Room 2S07, Quarry House
Quarry Hill
Leeds
LS2 7UE

A paper copy of this consultation document is available on request, using the e-mail address, above. If you have any questions about the content of this consultation then please send them to: GFprescribing@dh.gsi.gov.uk

If you wish to do so, you can request that your name and/or organisation be kept confidential and excluded from the published summary of responses.

Please note that we may use your details to contact you about your responses or to send you information about our future work. We do not intend to send responses to each individual respondent. However, we will analyse responses carefully and give clear feedback on how we have developed the implementation plan as a result.

Comments on the consultation process

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

Consultations Coordinator

Department of Health and Social Care

Room 2E26, Quarry House

Leeds

LS2 7UE

e-mail: consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health and Social Care's Information Charter.

Any information received, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 2018 (the DPA 2018) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information you have provided we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding by the Department.

The Department will process your personal data in accordance with the DPA 2018 and in most circumstances this will mean that your personal data will not be disclosed to third parties.

Next Steps

The Department will collate and consider all responses to this consultation and will make a recommendation to the Minister for Health and Social Care, on the proposed legislation and its progress through parliament.

Annex 1 - Proposed 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 2006ⁱⁱⁱ:

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 2004^{iv} 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—

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“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;

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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).

References

ⁱ <https://www.coeliac.org.uk/gluten-free-diet-and-lifestyle/prescriptions/prescription-policies/>

ⁱⁱ Drug Tariff January 2018

ⁱⁱⁱ 2006 c.41

^{iv} S.I. 2004/629