Department of Health & Social Care

Report of Responses Following the Public Consultation on Gluten Free Prescribing

Availability of Gluten Free Food on Prescription in Primary Care

January 2018

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Department of Health & Social Care

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Executive summary

The Department of Health & Social Care launched a public consultation to seek views on whether or not to make any changes to the availability of gluten free (GF) foods that can be prescribed in primary care.

Staple GF foods are available on prescription to patients diagnosed with gluten sensitivity enteropathies, and have been since the late 1960s when the availability of GF foods was limited. GF foods are now readily available in supermarkets and a wider range of naturally GF food types are now available, so the ability of patients to obtain these foods without a prescription has greatly increased.

Changes to the prescribing of GF foods could save NHS resources and reduce the primary care prescription drugs bill by up to £22.4 million per annum[1].

Many Clinical Commissioning Groups (CCGs) now have limited types or units of GF foods available on prescription[2]. A number of CCGs provide only bread and flour; several have stopped prescribing all GF foods. CCGs were set up to ensure that their local populations receive the medicines and treatments they require, with locally managed resources. Differing approaches to the availability of GF foods is creating regional variations across England.

A public consultation was launched on 31st March 2017 and was open for submission of responses to 22nd June. 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.
- Option 2: To add all GF foods to Schedule 1 of the above regulations to end the prescribing of GF foods in primary care.
- Option 3: To only allow the prescribing of certain GF foods (e.g. bread and flour) in primary care, by amending Schedule 1 of the above regulations.

This report provides information about the consultation responses and the analysis undertaken, additional evidence that supported the Impact Assessment has been incorporated into the Impact Assessment which is published separately alongside this report.

The health minister's preferred option is option 3 - to restrict prescribing to certain GF products. This is likley to result in retaining a smaller range of bread and mixes, as the preferred product types following the consultation.

To implement changes to the availability of GF foods requires the amendment of Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004, and amending the list of approved GF products in Part XV of the Drug Tariff.

[1] Prescription Cost Analysis (England) 2016

[2] CCG websites and https://www.coeliac.org.uk/gluten-free-diet-and-lifestyle/prescriptions/prescription-policies/

1. Introduction

1.1. The Department of Health & Social Care (DHSC) launched a public consultation to seek views on whether any changes should be made to prescribing legislation on 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 the Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004, or restricting their availability by way of amending 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. In certain conditions some food and cosmetic preparations have the characteristics of drugs; these are known as "borderline substances" and include GF foods. Individual GF food products are submitted by manufacturers for inclusion in the Drug Tariff for consideration by the Advisory Committee on Borderline Substances (ACBS). The committee recommends products for inclusion on the Drug Tariff based on product type and cost effectiveness, indicating their suitability to be prescribed in primary care.

1.3. GF foods are prescribed for people suffering from established gluten sensitive enteropathies, which include coeliac disease. When someone has coeliac disease their small intestine becomes inflamed if they eat food containing gluten. This reaction to gluten makes it difficult for them to digest food and nutrients. Gluten is found in foods that contain wheat, barley and rye (such as bread, pasta, cakes and some breakfast cereals). Screening for coeliac disease involves a two-stage process; a blood test to help identify people who may have coeliac disease and a biopsy to confirm the diagnosis. For patients who may have dermatitis herpetiformis (an itchy rash caused by gluten intolerance) a skin biopsy may be taken to confirm it.

1.4. Staple GF foods have been available on prescription to patients diagnosed with gluten sensitivity enteropathies since the late 1960s when the availability of GF foods was limited. GF foods are now readily available in supermarkets and a wider range of naturally GF food types are available, meaning that the ability of patients to obtain these foods without a prescription has greatly increased.

1.5. Many CCGs have made changes to local prescribing formularies and have restricted or ended supply of GF food[3]. This regional variation is leading to inequality of access. The prescribing position in CCGs in England (July 2017) is shown in Table 1. This concern was reflected in responses from many patients and other respondents. See Chapter 4.

Table 1 - CCG Prescribing Status

Prescribing Arrangements (July 2017)	**Number of CCGs**
Following Coeliac UK guidelines	78
Ended all GF foods on prescription (for all patients)	25

[3] https://www.coeliac.org.uk/gluten-free-diet-and-lifestyle/prescriptions/prescription-policies/

No restrictions	4
Other restrictions (type, quantities)	102

1.6. The national charity - Coeliac UK[4] - provides advice and guidance to patients with coeliac disease on following a GF diet, and has a range of resources to support them. They provide recommendations on the units of GF foods that patients should be prescribed based on their gender, age and whether they are pregnant or breastfeeding. CCGs often use these guidelines to inform local prescribing formularies.

1.7. The consultation document set out three options which were:

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

1.8. DHSC launched the consultation on 31st March 2017 and it closed on 22nd June 2017. It received 7941 responses. These included 7549 online responses, 250 e-mails, and 142 letters/paper response forms.

1.9. These responses have been read and evaluated and this report summarises the main themes that emerged and provides a breakdown of responses and respondent type.

[4] https://www.coeliac.org.uk/home/

2. Awareness and Engagement Activities

2.1. The Department decided to consult on the proposals to change the prescribing of GF foods given the potential impact on patients.

2.2. As part of awareness and engagement activities policy officials wrote to a range of organisations, which included, Coeliac UK, the British Specialist Nutrition Association (BSNA), and the Royal College of General Practitioners, to inform them of the public consultation. This encouraged a wide response rate from a range of organisations, patients and interested stakeholders.

2.2.1. Stakeholder meetings were held with Coeliac UK and the BSNA, along with representatives from Juvela and Glutafin (suppliers of GF foods).

2.2.2. Telephone discussions took place with 18 representatives from CCGs; some of which covered multiple and/or regionally clustered CCGs. Many CCGs had already made local changes to the prescribing of GF foods and some shared their findings from local consultation exercises. A couple of CCGs were able to share their analysis on patient impact when changes had been made in previous years.

2.3. The consultation was run on the Gov.UK digital platform and the GF page had 14277 hits during the live consultation period. Policy officials shared a link to the GF page with key stakeholders. In addition the Department's communication team utilised "Twitter" to publicise the consultation.

2.4. The national charity, Coeliac UK, promoted the consultation and encouraged their members to respond, they included a link on their website which enabled patients to locate the consultation and submit responses as patients or parents/carers of patients.

2.5. The British Dietetic Association (BDA) also promoted the consultation and encouraged its members to submit a response.

2.6. Correspondence was received from Members of Parliament on behalf of their constituents, although this mainly related to changes made at CCG level and did not directly relate to the national consultation. In our responses to such correspondence we included a link to the national consultation to enable correspondents to respond.

2.7. NHS England (NHSE) announced their plans to review provision of items which should not routinely be prescribed in primary care; they launched a public consultation[5] which closed on 21st October, this referenced the DHSC GF consultation. We will continue to work with NHSE, NHS Clinical Commissioners (NHSCC), CCGs, patients and industry on next steps.

[5] https://www.engage.england.nhs.uk/consultation/items-routinely-prescribed/supporting_documents/Consultation%20Items%20not%20routinely%20prescribed%20in%20primary%20care%20FINAL1809.pdf

3. Summary of Responses

3.1. A total of 7941 responses were received, of these 7549 were submitted on-line; 250 via e-mail to a dedicated GF mailbox, and 142 postal response forms/letters.

3.2. The Department's aim was to seek views from a wide range of interested parties, it was not a straight forward "vote" based upon numbers answering "yes" or "no" to the pre-determined questions. The response form was designed to allow respondents to state a "yes" or "no" answer and add the context of their response through an explanatory narrative. The following paragraphs show in detail the number of responses for each question, and a full evaluation follows in Chapter 4. Please note not all respondents answered every question.

Table 2: Q1 Do you think that GF foods should be available on prescription?

	Yes	No	Not Answered	Total
Number	6459	1456	26	7941
Percentage	81.3%	18.3%	0.3%	

Table 3 - Q2 Do you think GF prescribing should be restricted to certain foods?

	Yes	No	Not Answered	Total
Number	5582	2249	110	7941
Percentage	70.3%	28.3%	1.4%	

Table 4 - Q3 Do you think the range of bread products available on NHS prescription should be limited?

	Yes	No	Not Answered	Total
Number	3737	4062	142	7941
Percentage	47.1%	51.2%	1.8%	

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 categorised into "respondent type" as follows:

Table 5 - Respondent Type and Numbers

Respondent Type	Number of Responses
Charity	2
Clinical Commissioning Group (CCG)	125
GP Practice	10
Health Professional	1150
Member of the Public	259
Other	131
Other NHS Organisation	83
Parent/Family Member	712
Patient	5420
Private Company/Manufacturer	35
Professional Association	14

A breakdown of replies to questions, by respondent type, is contained in Annex A.

4. Evaluation of Responses

Literature Review

4.1. As part of the consultation process policy officials undertook a review of the information provided. This involved; accessing information contained in journal articles, reading and reviewing content, reviewing website content, summarising key points and relevance by theme. Literature was collated and scrutinised for relevant and factual information linking to the evidence requested in the consultation stage Impact Assessment.

4.2. Many of the key stakeholders provided comprehensive referencing to support information provided, this was reviewed and is contained in the updated Impact Assessment. Issues relating to health inequalities have been included in a separate Equality Impact Assessment (EqIA) document.

4.3. Both these documents will be published alongside this report.

Points of common agreement

4.4. Several points of agreement were evident from the responses received. These have been summarised below:

4.4.1. It was agreed by many respondents that Coeliac Disease (CD) is a disease state and that food is like a medicine for those patients and adherence to a GF diet is the only way of managing the condition and preventing further ill health related to CD.

4.4.2. The cost to purchase formulated GF food from retail outlets is more expensive than non-formulated GF food. This is especially the case for bread products where the gap between these products is more significant.

4.4.3. The quality of prescription products when compared to shop bought products can differ. Some prescription products are fortified to provide additional nutrients to patients to avoid malnutrition or vitamin deficiency.

4.4.4. The availability of GF foods is not always consistent and many smaller/local shops do not always stock a range of GF food. GF food is not routinely available in food banks or budget supermarkets. For patients/parents/carers that rely on food banks, they will need to select foods that are naturally GF such as meat, fish, rice, fruit and vegetables to ensure they adhere to a GF diet.

4.4.5. Patients in rural areas may depend on pharmacy deliveries for their GF foods, and may have difficulty in obtaining GF supplies from local shops.

4.4.6. The shelf life of fresh bread products can lead to waste if not collected from the pharmacy in a timely manner. The patient has to rely on freezing surplus fresh bread to avoid waste as pack sizes can often contain 6 - 8 loaves.

4.4.7. The local changes made by CCGs have led to inconsistencies for patients in England and this is causing inequality in access to GF food on prescription.

4.4.8. There are also many different approaches between CCGs which have led to inequality of access to ranges, types or quantities of GF food available on prescription.

4.4.9. Some CCGs have made changes without consultation, this has excluded patients, their representatives and others from having a say in how their local services are delivered.

4.4.10. Pharmacies are set up and managed to issue medicines and medical supplies and are not equipped to deal with holding large stocks of foods which often have a short shelf life, or are bulky.

4.4.11. Out of pocket expenses (OOPE) can be significant on some GF products, especially on fresh bread. Some CCGs have managed these out of the system through alternative GF supply models.

4.4.12. All GF food products listed in the Drug Tariff are "branded" products, whilst some retail outlets supply generic/own brand GF products.

4.4.13. The ACBS "recommended" list contains staple GF products, yet prescribing data[6] shows that luxury products such as cakes, pastries and sweet biscuits are prescribed. The majority of respondents agreed that only staple products should be available at NHS expense.

Main issues raised

4.5. GF foods are not consistently available in local shops or budget supermarkets. There is often unreliable stock and/or limited range in larger supermarkets, products may also have short expiry or "use by" dates. Certain brands of GF food are not available to buy in supermarkets, limiting patient choice.

4.6. The majority of respondents who favoured option 3 requested bread and mixes to remain on prescription due to; inconsistencies in availability, taste differences between prescription only products and those available in supermarkets, the price differences (especially bread), and accessibility, especially those who relied on pharmacy deliveries. Patients stated that GF mixes offered a more flexible option as they could be used at home to make a variety of foods.

4.7. Many respondents stated that the money spent on GF food could be better utilised across the NHS, and as GF food is not a medicine it should not be provided by the NHS. It was also stated that patients with other food intolerances or allergies do not get their food on prescription.

4.8. Parents or carers of children have requested that GF staples, especially bread, remain on prescription to prevent children feeling "different" to their peers, for example, the ability to take a packed lunch (sandwiches) to school. Some CCGs have retained GF prescribing for those under 18. Additionally this group are less likely to make their own dietary choices; this is especially the case for young children, as they rely on a parent/carer to purchase and prepare their meals. Information provided through the consultation stated that the lack of adherence to a GF diet could impact on the growth rate of children, delay puberty and make them susceptible to other auto immune conditions.

[6] Prescription Cost Analysis (England) 2016

Key themes

4.9. Many free text responses were consistent across respondents from different types, e.g. patients, carers, healthcare professionals and others. These have been collated below.

Accessibility

4.10. It was stated by patients and carers that prescriptions form a reliable and accessible source of GF staple foods.

4.11. Respondents said that those without transport or housebound patients, struggled to obtain GF food and that collection or home deliveries from a pharmacy were a convenient arrangement.

Adherence to a GF Diet

4.12. The importance of adherence to a strict GF diet is the only way in which coeliac disease can be managed. A strict GF diet avoids ill health and additional expense of treatment on the NHS. Evidence was provided by a health professional showing that patients who consume gluten in their diet could significantly impact their longer term health. This is detrimental to society and an additional burden on the NHS.

4.13. Many patient respondents said that a prescription for GF food helped them to adhere to a GF diet, especially for newly diagnosed patients. Respondents stated that the prescription route meant that patients felt supported by their GP and were more likely to access an annual health review, as recommended by the National Institute for Health and Care Excellence (NICE).[7]

4.14. Respondents acknowledged that it was important to follow a balanced healthy diet with the right mix of carbohydrates, which often consisted of formulated GF food.

Affordability of GF foods

4.15. Respondents said that GF foods remain substantially more expensive than their gluten containing equivalents.

4.16. Many respondents reported an adverse impact on the family food shopping bill, of up to £10 per week should they have to purchase their own GF food. (Patient respondents and Coeliac UK). This was compounded if the household had more than one coeliac patient, e.g. siblings, or a parent requiring GF food.

4.17. As noted in the consultation document it was highlighted that the cost of GF foods to the NHS was substantially higher than what is charged in a supermarket. This is because the price the NHS pays includes an amount for dispensing fees and delivery costs, and the GF formulated prescription food is often fortified with additional nutrients that may be lacking in a coeliac patient's diet.

Appropriate use of NHS resources

4.18. Evidence suggests the NHS faces higher prices for formulated GF foods than patients, for example through increased delivery costs when handling fresh food (that is, pharmacies are less well-equipped to handle fresh foods than a supermarket is). Table 6, below, based on evidence from CCGs, illustrates this difference.

[7] National Institute for Health and Care Excellence NG20 (2015) Coeliac disease: recognition, assessment and management

Table 6: Relative pricing of GF foods

Gluten-Free (GF) product	Clinical Commissioning Group (CCG)	CCG estimate of cost of GF product on prescription to the NHS	CCG estimate of cost of GF product in supermarket	Supermarket own-brand price of gluten-containing equivalent(s)[8]
3 bags of gluten-free pasta (500g)	Herefordshire	£20.97	£5.04	£3.60
1 bag of gluten-free pasta (500g)	West Hampshire	Between £2.72 and £11.25	Between £1.35 and £2	£1.20
1 bag of gluten-free pasta (500g)	Telford	Between £3.60 and £6.60	Between £1.50 and £1.99	£1.20

4.19. Evidence from the CCGs suggests that the NHS pays much more than the consumer for the same gluten-free products. Upon further investigation, there is little transparency on how NHS costs are comprised. In discussion with CCGs, the general consensus was that costs are shared between the manufacturers, a dispensing fee, a pharmacy fee and a delivery charge. Again, this may mean that the costs to consumers are overestimated.

4.20. Many respondents stated that GF food for a coeliac patient was like a medicine and should remain on prescription. Others felt that it was not a medicine and should not be available on the NHS and that GP services should not be used as grocers.

4.21. Some respondents said that the money spent on GF foods could be allocated elsewhere in the NHS, and that some prescribed GF food consisted of luxury items, e.g. part-baked bread, biscuits.

4.22. Some respondents were surprised to hear that food could be obtained on prescription, whilst some patients with coeliac disease stated that they preferred to make their own choices of either formulated GF food, or naturally GF food, so did not obtain a prescription, but sought a wider variety in retail outlets.

4.23. Respondents stated that GF food costs per patient equated to approximately £180 per patient per year, making it a cheap and effective "treatment" for coeliac disease. Whilst others felt that providing any food on prescription was a waste of taxpayers' money, and this should be re-invested in other treatment areas.

4.24. It was noted in responses that the prescribing route was inefficient as it required the GP to review the list of ACBS approved products and vary prescriptions according to the patient's preference. This was viewed as a waste of GP time, unless an annual review was taking place.

4.25. GF products prescribed are "branded" products; it was felt that there should be "generic" versions available, at a pre-determined price, or a "capped" price.

[8] Data taken from www.sainsburys.co.uk

4.26. GF products, especially fresh bread have a short shelf life which can contribute to waste; this is especially the case if the patient does not collect their GF food from the pharmacy once the prescription has been fulfilled. If patients do not have the capacity to store/freeze these products this can also lead to food waste.

Availability of GF foods

4.27. Respondents from the patient group said that bread and flour obtained on prescription formed a large part of their staple diet. They expressed a wish to retain supplies of GF food either on prescription or via an alternative route.

4.28. It was stated that many local shops/convenience stores and budget supermarkets did not stock GF foods, and there was reported inconsistency in stocks in large supermarkets.

4.29. Others felt that GF products were now widely available in supermarkets, budget stores and on-line which enabled patients to buy their own, making the case for ending GF prescriptions.

Dietary and Nutrition Advice

4.30. Many patients agreed that access to dietary advice supported their ability to follow a GF diet. Some said they had either no dietary advice, or that this was limited. Those patients whose CCGs had ended the prescribing of GF foods often no longer had an annual review of their condition, unless visiting their GP for another health reason.

4.31. Nutritionists said that when they were involved in a patient's health care they were able to look at the whole aspect of the diet and provide specific advice about that patient's needs, which could fluctuate and be impacted by other factors, for example, another medical condition.

4.32. Dieticians stated that it was crucial to avoid malnourishment in patients and to ensure they had an adequate balance of nutrients to remain healthy. They reported that GF prescription food helped patients maintain a healthy diet and fortified GF food enabled patients to receive additional nutrients as opposed to requiring vitamin or mineral supplements.

Dieticians, patients and other healthcare professionals said that food labelling had improved and this helped patients make informed choices about their diets. They were concerned that without GF fortified foods patients could suffer from malnutrition.

Health costs of untreated coeliac disease

4.33. Coeliac patients can develop other longer term health conditions if they do not adhere to a GF diet. This would result in additional treatment costs to the NHS. An estimate of these was set out in the consultation stage impact assessment, which has been updated to reflect information submitted as part of the consultation process.

4.34. Respondents provided references and literature reviews to supply additional evidence which has been reviewed and evaluated as part of the updated impact assessment.

Health inequalities

4.35. Many respondents felt that as coeliac patients and treatment for the condition was through the provision of GF food, then they were disadvantaged when compared to patients that required a medicine or medical intervention, for another clinical indication.

4.36. Concerns were raised over a number of inequalities to particular groups should any changes be made to the provision of GF food on prescription. These are explored in Chapter 5, and detailed in the published Equality Impact Assessment.

Quality

4.37. Respondents stated that the quality of supermarket GF products varied and were often inferior to those obtained on prescription. Bread products on prescription are often fortified with additional nutrients.

4.38. Patients felt that the GF flour was often unusable and led to waste, many respondents stated that they preferred a GF mix which contained other ingredients and allowed them to make more palatable and flexible GF products, such as bread rolls or a loaf of bread.

4.39. Some respondents reported that GF formulated foods often contained higher levels of fat and/or sugar to improve their palatability which did not necessarily contribute to healthy eating.

System Abuse and Waste

4.40. Some respondents stated that the prescription system for GF food is inappropriately misused, and some patients; obtain quantities of GF food to feed the whole family, over order GF food and stock pile supplies, which can lead to food wastage. It was reported that some luxury items continue to be prescribed.

4.41. Respondents stated that some people follow a GF diet as a lifestyle choice, believing that this is a healthy diet and that this leads to dietary fads and puts at risk the availability of GF items in shops. Others felt that GF prescriptions were their entitlement and should not be restricted or ended.

Variety

4.42. Some patients said that it remained important for them to have choice in their GF products. Health professionals reported "taste fatigue" if patients just had the same products continuously, as such a wide variety of products should remain.

Key Stakeholder Responses

4.43. In response to the consultation many organisations submitted completed questionnaires or letters setting out their views and those of their members. These have been considered and evaluated as part of the analysis. The main points of their correspondence/questionnaires have been summarised by respondent.

Coeliac UK's Response

4.44. Coeliac UK is the largest coeliac disease charity in the world with over 60,000 members. They represent views of patients and encouraged individuals to respond to the consultation. Policy officials met with the CEO and their Director of Policy and Campaigns to hear their views, and Coeliac UK also submitted a comprehensive written response. The key points raised in Coeliac UK's response were:

- Following a GF diet is the only treatment of coeliac disease and GF prescriptions help with adherence.
- Dietary advice to patients is inconsistent across England.
- Following a GF diet can be financially burdensome on low income families, especially those with more than one coeliac patient in the household.

- GF food on prescription helps address inequalities and is a cost effective means of getting staple GF foods to patients.
- A rationalisation of the GF foods in the Drug Tariff is needed.
- A competitive procurement process for GF food would deliver better value for money for the NHS.

British Specialist Nutrition Association (BSNA) Response

4.45. The BSNA represents the manufacturers of foods designed to meet the needs of people with special nutritional requirements, including GF foods. Policy officials met with the BSNA Director General and representatives from Glutafin and Juvela (manufacturers of GF food). The BSNA submitted a written response to the consultation which raised the following key points:

- GF food prescriptions are an important contribution to the successful management of coeliac disease.
- GF prescriptions should supplement the patient's diet.
- GF prescriptions provide a guaranteed reasonable supply of GF foods to assist patients in adhering to a GF diet.
- A review of the existing ACBSrecommended list should be undertaken to create a simplified list of staple products.
- A core range of products should be available to support patient choice.

British Dietetic Association (BDA) Response

4.46. The BDA represents the dietetic workforce, it is a trade union and professional body representing the professional, educational, public and workplace interests of its members. Membership includes; dietitions, practitioners, researchers, educators, support workers and students. They responded to the consultation with comments as follows:

- The cost of GF food remains significantly more expensive than gluten containing standard foods, this can impact patient's adherence to a GF diet.
- The availability of GF foods can be harder to access in smaller or budget shops, especially in rural areas, where on-line delivery from supermarkets may also be limited.
- Patient's adherence rates to GF diets vary depending upon demographic, clinical and psychosocial factors. In response to a BSNA survey, out of 1000 respondents 88% agreed that receiving GF foods on prescription was important to their adherence. Contact with a healthcare professional may also suffer if GF prescriptions were not provided.
- Commercially formulated GF foods are less likely to be fortified that their prescription counterparts. Additional nutrients are essential to a coeliac patient, and the risk of nutritional deficiency and poor diet may be reduced with products available on prescription.

Royal Colleges and the Royal Pharmaceutical Society

4.47. Responses were received from The Royal College of Nursing, The Royal College of GPs, The Royal College of Physicians, The Royal College of Paediatrics and Child Health, and The Royal Pharmaceutical Society. They were not supportive of the removal of GF foods at NHS expense, though suggested other delivery models may be feasible and could make NHS cost savings. In summary their comments included:

- Certain GF foods should be available, especially to those patients on a low income, or who have reduced access, for example rural areas, limited mobility.
- GPs need to maintain their clinical judgement to identify and support the most vulnerable patients.
- There is a risk that patient health will be impacted if GF food is no longer available at NHS expense and this in turn would lead to increased costs for the NHS.
- Equal access to a GF diet should be maintained to minimise the impact of health inequalities.
- A national voucher scheme should be instigated to reflect the Scottish GF Service which is pharmacy led, thus relieving GP time and making use of community pharmacists.
- Access to expert dietary advice and guidance needs to be in place to support coeliac patients in maintaining a GF diet, in addition to improved food labelling.

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

5.1. 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

5.2. 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.

5.3. The Secretary of State has a duty under the NHS Act 2006 (Section 1A) to secure an improvement in the quality of services. The release of funds from any GF food prescribing would be re-deployed into other parts of the system. He also has a duty under Section 1C to reduce inequalities. The Equality Impact Assessment published alongside this document details potential impacts and mitigation of policy changes.

5.4. A full assessment of our statutory duties, including our PSED duties will be published which will analyse the equality issues that have emerged from the consultation responses, some of the key themes that emerged are summarised below.

5.5. Families who are on low incomes are likely to feel a greater impact from any changes as they may currently be eligible for free prescriptions. Some households may have multiple coeliac disease members making the increased cost to their weekly food shopping more significant.

5.6. It is acknowledged that bread remains a staple part of many people's diet, including patients with coeliac disease. The impact of changes to the availability of GF foods on prescription could be greater on those who are experiencing economic deprivation as GF bread remains more expensive than its gluten containing counterpart.

5.7. Although coeliac disease is not a disability, patients with limited mobility and the elderly may have problems obtaining non-prescription GF items as they often rely on home deliveries by pharmacies. Whilst they can purchase GF foods on-line for home delivery by a supermarket or on-line retailer, many may not be able to quickly adapt to changes to access of GF food.

5.8. People with additional auto immune conditions could find themselves in a situation whereby their medication to treat that condition is provided on prescription, but their GF food is not. This may impact on them visiting their GP regularly and may risk detrimental ill health.

5.9. Respondents from the parent/carer group raised concerns about access of GF food for children and the elderly, as these groups were more likely to have their dietary choices made for them. Elderly patients and younger children often rely on GF prescriptions to support their meals which may be prepared by a parent or carer.

6. Alternative Delivery Models

6.1. As part of the consultation a number of organisations suggested alternative delivery models to ensure that patients continued to have access to GF food at NHS expense. These alternative delivery models are listed below.

Non-prescription route (Vouchers)

- Supermarket voucher scheme (pre-paid card) e.g. Vale of York CCG
- Pharmacy voucher scheme ("prescription" voucher) e.g. Rotherham CCG
- Healthy Start Scheme NHS voucher, this is a means tested voucher to provide milk, fruit and vegetables, infant formula and vitamins.

Supply chain improvements

- Supply chain improvement (to avoid Out of Pocket Expenses (OOPE)) and improved procurement by NHS

Dietetic Service

- A GF supply service led by dieticians who understand nutritional requirements for patients at their various life stages, this would ensure that nutrition was adapted to that individual's needs. Any health issues could be quickly identified and referred to other appropriate services.

Revised Prescription (FP10)

- Changes to quantity, costs, patient type, or product type in any combination (see chapter 7).
- Generic prescription wording e.g. "GF food item - x units". Patients could decide which staple GF item to obtain.

The advantages and disadvantages of these alternatives are summarised in table 6.

Table 6 - Summary of Suggested Delivery Models

Option	Advantages	Disadvantages
Supermarket voucher scheme	Widely accepted in the retail sector Patient convenience Free up GP time Less prescriptions to process	Expensive administration Opportunity for fraud (e.g. not used on GF products) Could be used on non-staple GF items (conflict with healthy eating messages) Could increase demand as those who don't currently obtain prescriptions calim vouchers
Pharmacy voucher scheme	Tailored patient approach Dietetic support and advice	Separate negotiations by each CCG with pharmacies/retail outlets[9] Opportunity for fraud (dependent upon local scrutiny)
Healthy Start Scheme - NHS food vouchers	Means tested benefit Wide range of retailers already partake	Vouchers are for pregnant women and children under 4 - coeliac disease is not often diagnosed in very young children
Supply chain improvements	Fewer out of pocket expenses Issues of availability improved	Challenge by manufacturers Requires investment of time and resources to establish
Dietetic service	Tailored patient approach Advice and guidance to patient from nutrition expert Cost savings as based on patient need - avoid over ordering/stock piling	Workforce issues - e.g. number of NHS dieticians Requires investment of time and resources to establish
Revised prescription route (changes or generic prescribing)	Fewer products for GP to review/select Patient choice of product to suit own preferences Reduce waste Support adherence to GF diet	Restrictions for patient choice and preferences Inconsistency/confusing pharmacy dispensing e.g. 400g loaf, 525g loaf = 1 item

[9] There is already provision in Directions for pharmacies to provide a ‘gluten free food supply service’ as an enhanced service.

7. Consultation - Suggested Options

7.1. The public consultation focussed on three options:

- Option 1 - Make no changes to the legislation in respect of prescribing GF foods
- Option 2 - End all prescribing of GF foods.
- Option 3 - Restrict the type of GF foods available on NHS prescription.

Option 3 focussed on the restrictions to the types of GF food that could be made to generate savings whilst ensuring patient health was not impacted.

7.2. Respondents to the consultation suggested a wide range of options that could be more flexible to meet the needs of patients and still result in savings to the drugs bill. These **suggested options** have been grouped into four areas and summarised below.

Product types

7.3. Make a reduction in the range of GF foods listed in the Drug Tariff.

7.4. To allow only ACBS approved products to be prescribed, ensuring luxury items are not prescribed.

7.5. Restrict to bread only - respondents stated that bread is a staple part of their diet and it remains the most expensive single GF formulated product when compared to gluten containing bread.

7.6. Restrict to the most popular types of products currently prescribed. The most popular items are white and brown sliced loaves.

7.7. To retain "mixes" as opposed to GF flour - patients stated that mixes were a versatile product which could be used to make a variety of products, e.g. bread rolls, pizza bases etc. and that GF flour was difficult to bake with.

Product quantities

7.8. Undertake a review of the number of GF units prescribed. As part of the consultation the majority of health professionals/clinicians stated that the national prescribing guidelines by Coeliac UK are used to decide the number of units a patient should receive on a monthly basis. Some respondents felt that this led to system abuse, (e.g. ordering their monthly entitlement even if not required), food wastage and stock-piling.

7.9. Pharmacists reported that product waste often occurred when repeat prescriptions were issued, ordered by the pharmacy and then not dispensed to the patient. This was especially the case with fresh bread products and led to waste and storage issues.

Price

7.10. Undertake a price review or price reduction in GF products listed in the Drug Tariff. A price reduction may encourage competition as happens with commercially available products. The Advisory Committee on Borderline Substances (ACBS) could be involved in a review to ensure fairness and consistency to manufacturers.

7.11. Introduce a price cap on GF products that the NHS would agree to supply, for example a maximum re-imbursement price for a GF product. This could reflect an average price evaluation to ensure fairness and equity to manufacturers.

7.12. Introduce a price freeze on all GF ACBS approved products.

7.13. Allocate a "lowest price" approach for all GF ACBS approved products, for all product types.

7.14. An option suggested by several respondents reflected that patients should contribute to the cost of their GF food, as everyone has to buy food, e.g. a part subsidy approach whereby a patient pays a contribution to the cost of their GF prescription.

Patient Status

7.15. Provide prescriptions for children only. Evidence provided in the consultation stated that children with coeliac disease could suffer by failing to thrive and grow, and delayed puberty. Children often have their food product purchases and meal choices made by a parent or carer. It is important that children can access a GF diet.

7.16. Concern was expressed by elderly patients that they rely on home deliveries of prescription items, including GF food, as mobility is an issue for them. They would be able to purchase GF foods on-line for home delivery. This patient group may take longer to adapt to any changes made in the prescribing of GF food.

7.17. To continue to provide prescriptions to those on low incomes. The prescription charge exemption categories already include those on certain benefits.

7.18. An option to provide prescriptions for those patients who have been newly diagnosed, e.g. for the first year, which would help patients adapt their diets and become accustomed to new eating habits.

Summary

7.19. The above options will be given further consideration to evaluate future savings.

8. Next Steps

8.1. The minister's preferred option is Option 3 - to retain a limited range of bread and mix products on prescription. This means that GF foods from the following categories will no longer be available for prescribing; biscuits, cereals, cooking aids, grains/flours and pasta.

8.2. Work will begin on amending the National Health Service (General Medical Services Contracts)(Prescription of Drugs etc.) Regulations 2004, Schedule 1, and then removing these products from the Drug Tariff.

8.3. Policy officials will engage with key stakeholders to ensure that the range of products that remain in Part XV of the Drug Tariff will be cost effective for NHS prescribing and provide patients with basic provisions to support adherence to a GF diet.

Annex A - Breakdown by Respondent Type

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

Charity

- 2 responses:
  - Coeliac UK
  - Age UK

	Q1. Do you think GF foods should be available on prescription in primary care?	Q2. Do you think GF prescribing should be restricted to certain foods?	Q3. Do you think the range of bread products available on NHS prescription should be limited?
YES	2	2	2
NO	0	0	0
NOT ANSWERED	0	0	0

Clinical Commissioning Groups (CCGs)

- 125 responses (some responses covered more than one CCG)
- 57 CCGs were identified as responding (some unable to attribute to a CCG as location not given)

	Q1. Do you think GF foods should be available on prescription in primary care?	Q2. Do you think GF prescribing should be restricted to certain foods?	Q3. Do you think the range of bread products available on NHS prescription should be limited?
YES	18	52	78
NO	106	67	40
NOT ANSWERED	1	6	7

GP Practices

- 10 responses

	Q1. Do you think GF foods should be available on prescription in primary care?	Q2. Do you think GF prescribing should be restricted to certain foods?	Q3. Do you think the range of bread products available on NHS prescription should be limited?
YES	10	6	8
NO	0	4	2
NOT ANSWERED	0	0	0

Health Professionals

- 1150 responses
  - Pharmacists
  - Medicines management managers
  - Community nutrition groups

	Q1. Do you think GF foods should be available on prescription in primary care?	Q2. Do you think GF prescribing should be restricted to certain foods?	Q3. Do you think the range of bread products available on NHS prescription should be limited?
YES	381	674	785
NO	766	459	344
NOT ANSWERED	3	17	21

Members of the public

- 259 responses

	Q1. Do you think GF foods should be available on prescription in primary care?	Q2. Do you think GF prescribing should be restricted to certain foods?	Q3. Do you think the range of bread products available on NHS prescription should be limited?
YES	172	151	121
NO	83	90	113
NOT ANSWERED	4	18	25

Other Respondents

- 131 responses
  - Students
  - Pharmacies
  - Retired health professionals

	Q1. Do you think GF foods should be available on prescription in primary care?	Q2. Do you think GF prescribing should be restricted to certain foods?	Q3. Do you think the range of bread products available on NHS prescription should be limited?
YES	73	80	82
NO	58	51	49
NOT ANSWERED	0	0	0

"Other NHS Organisation"

- 83 responses
  - General Practices
  - Medicines management teams
  - Dietetic Services

	Q1. Do you think GF foods should be available on prescription in primary care?	Q2. Do you think GF prescribing should be restricted to certain foods?	Q3. Do you think the range of bread products available on NHS prescription should be limited?
YES	51	41	35
NO	32	41	47
NOT ANSWERED	0	0	1

Parent/Family Member

- 712 responses
  - Parents of coeliac children
  - Spouses and/or carers of patients
  - Other relatives e.g. grandparents

	Do you think GF foods should be available on prescription in primary care?	Do you think GF prescribing should be restricted to certain foods?	Do you think the range of bread products available on NHS prescription should be limited?
YES	675	496	260
NO	36	209	443
NOT ANSWERED	1	7	9

Patients:

- 5420 responses

	Do you think GF foods should be available on prescription in primary care?	Do you think GF prescribing should be restricted to certain foods?	Do you think the range of bread products available on NHS prescription should be limited?
YES	5031	4049	2346
NO	372	1313	2999
NOT ANSWERED	17	58	75

Professional Associations Responses

- 14 responses
  - Medical Royal Colleges
  - Local Pharmaceutical Committees
  - Dietetic Associations

	Q1. Do you think GF foods should be available on prescription in primary care?	Q2. Do you think GF prescribing should be restricted to certain foods?	Q3. Do you think the range of bread products available on NHS prescription should be limited?
YES	12	9	7
NO	2	1	3
NOT ANSWERED	0	4	4

Private Company/Manufacturer

- 35 responses

	Q1. Do you think GF foods should be available on prescription in primary care?	Q2. Do you think GF prescribing should be restricted to certain foods?	Q3. Do you think the range of bread products available on NHS prescription should be limited?
YES	33	21	13
NO	2	14	22
NOT ANSWERED	0	0	0

Annex B - Question and Answer

1. 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.

2. 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.

3. What are the implications of not following a GF diet?

Non-adherence to GF diets among patients with gluten sensitivity enteropathies 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.

4. Why are gluten-free foods available on the NHS?

Gluten-free (GF) foods are available on prescription to patients diagnosed with gluten sensitivity enteropathies, including coeliac disease.

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.

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.

5. How much does the NHS spend on the prescribing of gluten-free foods?

Data from 2016 shows that nationally the NHS spent £22.4 million on the basic cost of GF foods. This mainly related to the prescribing of staple foods such as bread, flour and pasta but also to non-staple items including biscuits, cakes and pastries which were all prescribed at NHS expense. In addition to the basic cost, there are significant on-costs for Clinical Commissioning Groups to consider in the form of dispensing fees and the cost of primary care consultations to offer prescriptions.

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

The main societal benefit of spending in the NHS is the provision of health gains to patients. Despite inconsistencies in the provision in some supermarkets and other food outlets, availability of GF foods is such that patients can access a range of products without a prescription. More health gains would be generated if prescribing expenditure was reduced, and the funds used elsewhere in the NHS.

Today, GF foods are available in supermarkets and other food outlets where patients can purchase items in-store or online.

The consultation presented respondents with 3 options:

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 as now.

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 flour) in primary care, by amending Schedule 1 of the above regulations.

7. What option has the Government decided upon?

The Government has decided on option 3 to restrict GF prescriptions to certain foods. This would deliver savings to the NHS and help 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.

8. What were the common themes of the consultation?

Several common themes emerged, including:

- Affordability and range of gluten-free foods in supermarkets, particularly for those vulnerable groups on low incomes

- Adherence to a gluten-free diet

- Complications resulting from untreated coeliac disease

9. How many responses did the consultation receive?

The Department of Health & Social Care (DHSC) received almost 8,000 responses. These came from a wide range of stakeholders including patients, health care professionals, national associations, manufacturers of gluten-free foods, charities and NHS organisations.

10. What about changes already made in some Clinical Commissioning Groups (CCGs)?

It is for CCGs to decide how they commission local services to best meet the needs of their populations. Some CCGs have made changes that go beyond restricting to a staple range of products, and many have done so following patient engagement and/or consultation. They may

wish to undertake a review of their position taking into account patient feedback and the impact of their change. As a consequence they may or may not wish to adapt their position.

11. What happens next?

The DHSC will undertake work on the draft regulations which will restrict all gluten free products, with the exception of some bread and mix products. Amending the Regulations is a complex piece of work that will take some time to develop and implement.