

Dear Colleague

ADDITIONAL PHARMACEUTICAL SERVICES INTRODUCTION OF GLUTEN FREE FOOD SERVICE TIMETABLE, DIRECTIONS AND SERVICE SPECIFICATION

Summary

1. This Circular announces the introduction of the new Gluten Free Food (GFF) Additional Pharmaceutical Service on a trial basis. It details a timetable, includes Directions and the service specification and details remuneration arrangements under the Drug Tariff.

Background

2. The Advisory Committee on Borderline Substances (ACBS) provides advice to GPs on a UK basis on the circumstances in which it would be reasonable to prescribe particular medicinal products including some foods. As a consequence and as part of Pharmaceutical Services, community pharmacy contractors then dispense those individual occasional prescriptions for Gluten Free Foods written by GPs.

3. A new Gluten Free Food Additional Pharmaceutical Service (APS) is now being introduced on a limited period trial basis. The trial is scheduled to terminate on 31 March 2015 and has the objectives stated in Annex B.

Detail

4. The GFF APS is being introduced on a 12 month trial basis. Experience will be reviewed during 2014 in conjunction with community pharmacy contractors providing the new service, GPs, Health Board dieticians and patient representatives. This review will focus on the clinical benefit for the patients concerned and cost effectiveness for NHS Scotland, by comparison with the arrangements for dispensing of these items previously in force. The review will also identify what changes may be needed to IT systems in the event that the trial is to become a permanent service. Qualifying patients who do

November 2013

Addresses

For action

Chief Executives, NHS Boards

For information

Chief Executive
NHS NSS
Director of Practitioner Services,
NHS NSS

Enquiries to:

Shelagh Scott
Pharmacy & Medicines Division
1st Floor East Rear
St Andrew's House
EDINBURGH
EH1 3DG
Tel: 0131 244 2597
Email:
shelagh.scott@scotland.gsi.gov.uk
www.scotland.gov.uk

not wish to opt into the service and ineligible patients will continue to access prescriptions from their GP as at present.

5. Once the GFF Service is in place an eligible and qualifying patient will no longer have to request individual prescriptions for GF items from their GP. The patient will instead be able to register their condition with a community pharmacy of their choice, provided that the contractor concerned had opted in to providing the GFF APS. Access to the service would then follow the protocol arrangements detailed below in paragraph 7, enabling patients to access pharmacy dispensed staple GFF items. The quantity of GFF items a patient can have is based on a personalised clinical assessment, and the supply of GFF items will be in accordance with those GFF items that are covered within the formulary published by their local Health Board.

6. The Health Board Additional Pharmaceutical Services (Gluten Free Foods) (Scotland) Directions 2013 ("the GFF Directions") attached at Annex A and the service specification attached at Annex B detail who qualifies and is eligible to register for and use the new trial GFF APS. The GFF Directions provide the legal framework for GFF APS and apply from 13th January 2014.

7. The timetable for the introduction of this service is as follows:

From 2nd December: community pharmacy contractors to ensure their pharmacists familiarise themselves with the GFF service and start to liaise with local GP practices regarding the service, in accordance with local plans established by their Health Board.

From 20th January 2014: GPs and dieticians may start to issue eligible and qualifying patients with a referral form (Annex C) to indicate that due to their clinical condition they may register with an opting-in community pharmacy contractor for the GFF APS rather than requesting GFF items on prescription

Patients may register with an opting-in community pharmacy contractor of their choice for the GFF APS.

From 3rd February 2014: eligible and qualifying patients may start to have items directly dispensed by their community pharmacy in accordance with the GFF APS protocol as set out in Annex B, duly customised for their own clinical needs.

1st April 2014: The GFF Service trial period formally starts.

31st March 2015: The GFF Service trial period formally concludes.

8. As part of Pharmaceutical Services, community pharmacy contractors currently dispense individual occasional prescriptions for Gluten Free Foods written by GPs. The scope of GFF items which may be dispensed by community pharmacy contractors will be subject to a published local formulary determined by the NHS Board on whose Pharmaceutical List they are to optimise value for money and clinical effectiveness. Each local formulary will reflect existing good clinical practice and embrace only certain 'generic' staple GFF items. In order to assist Boards in

establishing their local formularies an initial list of products and the equivalent units that each product equates to will be supplied to them. Each Board will be responsible for maintenance of its own formulary. The scope of products and conditions are covered within existing ACBS advice.

9. As the GFF Service is being introduced on an initial trial basis a full electronic service will not initially be available and the following steps should be followed for each patient who wishes to take part in the trial:

- At the request of an eligible and qualifying patient a referral form with diagnosis and number of units allocated will be completed by the patient's GP or dietician (see Annex C). This form must be signed by the GP. The GP should agree with the patient the date on which prescribing of products will begin on the new service ensuring that the patient is issued with adequate prescriptions in the meantime.
- Patient will present their GFF APS referral form to the pharmacy of their choice and register for the service. Patient and pharmacist will sign the form to indicate that the patient is registered at that pharmacy. The pharmacy should retain the referral form for payment verification purposes. (To assist with evaluation of the trial it is initially a condition that the patient should maintain their registration with the first chosen pharmacy for the duration of the trial. The procedure to be used subsequently whereby a patient may register with an alternative pharmacy will be considered as part of the review of the trial.)
- The pharmacy should create a Pharmaceutical Care Record (PCR) for the patient and the assessment tool completed. The assessment tool should be completed at least annually thereafter.
- Any care issues should be referred to the patient's GP/ and or dietician.
- The pharmacist will then issue items by completing a CPUS form to include **the CHI number** of the patient concerned and the detail of the items supplied each month and submit this to PSD at the end of each month. **Payments will not be made unless the form is submitted to PSD and contains the patient's CHI number.**

10. In summary, for the duration of the trial period the community pharmacy contractor is required to complete and maintain the following written records and reimbursement claims:

- a. The GP referral form in the format of that in Annex C for each patient.
- b. A list of patients who have registered for GFF APS during the trial period and the months for which they were registered.
- c. A PCR for each patient registered for the GFF APS plus completed and updated assessment tool as appropriate.
- d. A completed monthly CPUS form for each patient including, the patient's CHI number plus the detail of the items dispensed.

Patient leaflet

11. A patient leaflet is being prepared to inform potentially eligible and qualifying patients of the scope and conditions related to the introduction of the GFF APS.

Pharmacist Training and Resource Pack

12. A training pack is being made available to all community pharmacy contractors and their support staff to help implement the service.

Amendment to Drug Tariff and consultation with Community Pharmacy Scotland

13. Community Pharmacy Scotland have been consulted on the contents of this Circular.

14. The Drug Tariff is amended with effect from 1 December 2013 to reflect the terms of this Circular.

Action

15. Health Boards should:

- copy this Circular to all Community Pharmacy contractors on their list and to Community Health Partnerships and GP practices in their area.
- by 31st December 2013 Health Boards should invite Community Pharmacy contractors on their list to register to provide the Gluten Free Foods Additional Pharmaceutical Service on the terms notified by this Circular including the signature and return to the Health Board concerned of a declaration in the form as detailed at Annex D.
- provide as soon as practical appropriate additional advice about local plans for the operation of the service in their area to both Community Pharmacy contractors and GP practices on their lists.

16. Community Pharmacy contractors wishing to opt in to the trial should formally confirm to their Health Board by 31st January 2013 their intention to do so, including signature of the required declaration in the form as detailed at Annex D

17. GPs, at their convenience but also having regard for the timetable outlined above for the introduction of this trial of a new service to start to issue GFF APS Referral Forms to those patients whom they are satisfied are both eligible and qualify for the service and who individually wish to take advantage of these trial arrangements.

Yours sincerely

Bill Scott

Chief Pharmaceutical Officer and Deputy Director, Pharmacy & Medicines Division

NATIONAL HEALTH SERVICE (SCOTLAND) ACT 1978

HEALTH BOARD ADDITIONAL PHARMACEUTICAL SERVICES (GLUTEN FREE FOOD) (SCOTLAND) DIRECTIONS 2013

The Scottish Ministers, in exercise of the powers conferred by sections 2(5), 27A, 27B, 28A and 105(7) of the National Health Service (Scotland) Act 1978¹, and all other powers enabling them to do so, hereby give the following Directions.

1. Citation and commencement

1.1 These Directions may be cited as the Health Board Additional Pharmaceutical Services (Gluten Free Food) (Scotland) Directions 2013 and shall come into force on 13th January 2014.

2. Interpretation

2.1 In these Directions, unless the context otherwise requires:

“the Act” means the National Health Service (Scotland) Act 1978;

“the Agency” means the Common Services Agency for the Scottish Health Service constituted under section 10 of the Act²;

“the 2009 Regulations” means the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009³;

“care home” means an establishment which provides a care home service as defined in paragraph 2 of schedule 12 to the Public Services Reform (Scotland) Act 2010⁴;

“consultation” means a consultation with a pharmacist under the Gluten Free Food service;

- “eligible person” means a person who at the time of initial registration, and at the time of any subsequent consultation fulfils the following conditions: : is a registered patient in terms of either the National Health Service (General Medical Services Contracts)

¹ 1978 c.29; section 2(5) was amended by the National Health Service and Community Care Act 1990 (c.19) (“the 1990 Act”), section 66(1); section 27A was inserted by the National Health Service (Primary Care) Act 1997 (c.46), section 27(2); section 28A was substituted by the Health Act 1999 (c.8) (“the 1999 Act”), section 57, and amended by the Primary Medical Services (Scotland) Act 2004 (asp 1) (“the 2004 Act”), section 8, and schedule 1, paragraph 1; section 105(7) was amended by the Health Services Act 1980 (c.53), Schedule 6, paragraph 5(1) and Schedule 7, the Health Services and Social Security Adjudications Act 1983 (c.41), Schedule 9, Part I, paragraph 24 and the 1999 Act, Schedule 4, paragraph 60. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998 (c.46).

² Section 10 was amended by the 1990 Act, section 66(2) and Schedule 10; the 1999 Act section 65(1) and Schedule 4, paragraph 44(a); and amended by the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13), Schedule 2, paragraph 2(4).

³ S.I. 2009/183, amended by S.S.I. 2009/209, 2010/128, S.I. 2010/231, S.S.I. 2011/32, 2011/55, 2012/36, S.I. 2012/1479, 2012/1916, 2013/235 and 2013/2042

⁴ (asp 8).

(Scotland) Regulations 2004⁵ or the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004⁶; and whose main or usual residence is not a care home,

and “eligible persons” shall be construed accordingly.

“Gluten Free Food Service” or “GFF Service” has the meaning ascribed in paragraph 3.1;

“patient record” means a record maintained for each recipient of GFF Service in accordance with paragraph 4 of Schedule 2;

“Pharmaceutical Care Record” means the NHS web based IT system in which the details of a pharmaceutical assessment and pharmaceutical care plan are recorded;

“qualifying person” means eligible persons who have been diagnosed by their GP with Coeliac Disease or dermatitis herpetiformis

“registration” means registration for the Gluten Free Food Service in terms of paragraphs 3 to 5 of Schedule 2, and “registered” shall be construed accordingly;

2.2 Other words and phrases used in these Directions have the same meaning as they have in the Act.

2.3 Any reference in these Directions

- (i) to a numbered paragraph, is a reference to a paragraph bearing that number in these Directions;
- (ii) to a numbered Schedule, is a reference to the Schedule to these Directions bearing that number; and
- (iii) to a numbered paragraph of a numbered Schedule, is a reference to a paragraph bearing that number in the Schedule bearing that number.

3. Description of the Gluten Free Food Service

3.1. The Gluten Free Food Service is a service for the provision of pharmaceutical care to persons who are registered to receive GFF Service by a person who is authorised to provide GFF Service in terms of paragraph 5. In addition, GFF Service registered persons may, where appropriate, be given advice, treatment or onward referral by authorised GFF Service providers to another NHS healthcare practitioner if they are deemed to be entitled to that service. Only qualifying persons can register for, and receive dispensings under the GFF Service.

⁵SSI 2004/115, amended by SSI 2004/215, 337 and 2006/247, SI 2007/289, SSI 2007/206,392 and 501 and 2008/27.

⁶SSI 2004/116, amended by SSI 2004/162, 217, 2005/336 and 2006/248, SI 2007/289, SSI 2007/205, 393 and 502 and 2008/27.

3.2 The services which are comprised in GFF Service are specified in Schedule 1.

4. Health Board duty to arrange for a Gluten Free Food Service

4.1 Until otherwise directed, Health Boards have a duty to arrange for the provision of GFF Service for eligible and qualifying persons in their area as an additional pharmaceutical service.

5. Persons authorised to provide the Gluten Free Food Service

5.1 Health Boards may only enter into arrangements for the provision of GFF Service with:

- (a) a person who is a registered pharmacist; or
- (b) a person other than a registered pharmacist who, by virtue of section 69 of the Medicines Act 1968⁷, is taken to be a person lawfully conducting a retail pharmacy business in accordance with that section;

and, in the case of both (a) and (b) who

- (i) is on the pharmaceutical list maintained by the Health Board in terms of regulation 5 of the 2009 Regulations⁸; and
- (ii) undertakes that all GFF Service shall be provided either by or under the direct supervision of a registered pharmacist.

6. Compliance and Conditions

6.1. The arrangements made by a Health Board in accordance with paragraphs 4 and 5 shall include the terms and conditions specified in Schedule 2, with which the provider of GFF Service shall be obliged to comply.

7. Remuneration and reimbursement for the provision of a Gluten Free Food Service

7.1. Remuneration for the provision of GFF Service will be paid at nationally negotiated rates as set out in the Drug Tariff.

7.2. The prices and methodology for calculating reimbursements to a GFF Service provider for any GFF items that he or she may supply to patients registered for GFF Service will be in accordance with the provisions set out in Part 1 of the Drug Tariff.

7.3 Further detail on remuneration for the provision of GFF Service is specified in Schedule 3.

⁷ 1968(c.67) section 69 was amended by the Pharmacy Act 1954 (c.61), Schedule 16, the Pharmacists (Fitness to Practise) Act 1997 (c.19), section 1 and Schedule paragraph 4, and the Statute Law Repeals Act 1993 (c.50) and by SI 2007/289 and 2007/3101.

⁸ Regulation 5 was amended by S.S.I. 2011/32.

Signed by authority of the Scottish Ministers

W Scott
Scottish Executive A member of the Senior Civil Service
November 2013

NATIONAL HEALTH SERVICE (SCOTLAND) ACT 1978

HEALTH BOARD ADDITIONAL PHARMACEUTICAL SERVICES (GLUTEN FREE FOOD SERVICE) (SCOTLAND) DIRECTIONS 2013

SCHEDULE 1

SERVICES TO BE PROVIDED AS A GLUTEN FREE FOOD SERVICE

1. The service comprises the following service only to those patients referred by a GP within the patient's normal GP practice, or dietician acting on their behalf, as being eligible and qualifying for the provision of the service by virtue of having been diagnosed as being a Coeliac or having dermatitis herpetiformis. The service includes the necessary consultations with a pharmacist and advice on the condition(s) that the patient presents and, where the pharmacist considers it appropriate, the prescription and supply of GFF items in accordance with any formulary laid down by the NHS Board in whose area the contractor is listed and in accordance with the protocol laid down in Annex B to this Circular. Where the pharmacist considers the patient's condition is one that requires to be considered by another health care professional e.g. a GP or dietician; he or she will refer the patient to that person.
2. The products that can be prescribed and supplied by the pharmacist are listed in a locally set formulary, which may be developed by the NHS Board in whose area the contractor is located. These will be developed from the national resource that has allocated unit equivalence for each product.

SCHEDULE 2

TERMS AND CONDITIONS OF THE PROVISION OF A GLUTEN FREE FOOD SERVICE

1. A GFF service provider must not advertise or offer incentives to the public to register for GFF service, or set targets for employee pharmacists or staff to recruit people for GFF service or for any other aspects of GFF Service.
2. A GFF service provider may only issue or display the publicity material and patient information leaflet made available by Scottish Ministers in respect of GFF service and the provision of GFF service, or from their Health Boards.
3. Where a person is an eligible and qualifying person and wishes to register for the service, a GFF service provider must ensure that:
 - (a) a copy of the written referral form from a GP within the GP practice normally used by the patient, or dietician acting on the GP's behalf but signed by the GP has been presented and has not been rescinded;
 - (b) the registration process is undertaken in accordance with procedures specified by the Scottish Ministers included as laid down at paragraph 3.1.8 in Annex B to the NHS (P) Circular giving notice of the introduction of the GFF Service;and
 - (c) a patient record is established.
4. For the purposes of GFF Service the 'patient record' is a pharmacy retained record (paper and/or electronic) that as a minimum must include:
 - (a) the name and address of the patient;
 - (b) where relevant, the name and address of the person who gave consent to, or applied for, the registration and that person's relationship to the person who is registered;
 - (c) the grounds for the patient's eligibility to register for GFF Service and the number of units they are entitled to; and
 - (d) the services provided to the registered patient as GFF service, to include:
 - (i) details of the advice or treatment provided;
 - (ii) the date on which each of the above was provided;
 - (iii) with respect to dispensings of GFF foods, the name, quantity, form and brand of any product supplied; and
 - (iv) if the patient was referred to another NHS healthcare practitioner, the name of that practitioner, the date of the referral and the reasons for the referral;
 - (e) Patient Care Record (PCR) provided for GFF Service should be completed for each patient
5. GFF Service can be provided to a patient only from the premises at which the patient is registered for GFF Service.

6. Subject to the provisions of any Regulations made under section 69 of the Act, all items supplied for GFF service shall be supplied free of charge.

7. A GFF Service provider is to use GFF Service stationery provided in the training pack if so required by their NHS Board to record details where a patient registered for GFF Service:

- (i) receives a consultation;
- (ii) is dispensed with GFF items under the service;
- (iii) is referred to another healthcare practitioner;
- (iv) is no longer eligible for GFF Service and registration must be withdrawn.

8. Where a GFF Service provider supplies GFF Service he or she must do so in accordance with paragraph 2 of Schedule 1.

9. The supply of GFF items is to be performed by or under the direct supervision of a pharmacist.

10. Where the pharmacist referred to at paragraph 9 is employed, the pharmacist must not be one:

- (a) who, has been disqualified under section 29B(2) of the Act⁹, or
- (b) who is suspended by direction of the Tribunal, or
- (c) who is the subject of a corresponding decision in England, Wales or Northern Ireland.

11. In providing GFF Service a GFF Service provider shall do so:

- (a) having regard to and, where required, in compliance with, stated standards, administrative guidance, and training requirements published, that is from time to time produced by Scottish Ministers;
- (b) in conformity with the standards generally accepted in the pharmaceutical profession.

12. The provisions at paragraph 12 of Schedule 1 of the 2009 Regulations with regard to and referred to as a “complaints procedure” shall apply to the provision of GFF Service.

⁹ Section 29B was inserted by the Health Act 1999 (c.8), section 58, and amended by the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13) (“the 2005 Act”) section 26 and Schedule 3 in terms of SSI 2006/121.

SCHEDULE 3

REMUNERATION FOR THE GLUTEN FREE FOOD SERVICE

1. Where a provider of Gluten Free Food Service complies fully with these Directions, payment for the provision of a Gluten Free Food Service will be in accordance with the arrangements set out in the Drug Tariff.
2. During the initial trial period of the Gluten Free Food Service which extends to 31 March 2015, remuneration will relate whether the contractor concerned has accepted the Health board's invitation to offer the service and continues to do so, to any qualifying and eligible person seeking to access the service and not to the numbers of patients registered.
3. Health Boards will be entitled to take such reasonable steps as are necessary to ensure that GFF APS providers are:
 - (a) providing GFF service as specified in Schedule 1 and complying with the provisions to all patients seeking to register for the service with the provider; and
 - (b) only displaying the agreed patient information leaflets and publicity materials made available by Scottish Ministers in respect of the GFF Service.
4. Payments made to providers for providing GFF Service will be subject to post-payment verification checks and investigation by the Agency.
5. Where after suitable investigation a Health Board is satisfied that a GFF service provider is not providing the services listed in Schedule 1 and/or complying with the provisions of Schedule 2, but is receiving payment in terms of this Schedule and the rates set out in the Drug Tariff, it may (without prejudice to any other action which may be open to it):
 - (a) write to the provider advising of the conclusion reached by the investigation;
 - (b) inform the provider that payments will be stopped with immediate effect; and
 - (c) recover any payments made to the provider under this Schedule and the Drug Tariff in respect of any period(s) when the provider was not providing the services specified in Schedule 1 and/or complying with the provisions of Schedule 2.

GLUTEN FREE FOOD (GFF) ADDITIONAL PHARMACEUTICAL SERVICE TRIAL SERVICE SPECIFICATION

1. Service Aim and Objectives

1.1 The objectives for GFF APS are to:

- Support the provision of direct NHS pharmaceutical care to patients with coeliac disease or dermatitis herpetiformis by providing a pharmacy led nationally consistent service;
- Make optimum use of clinicians' skills and empower the patients to actively manage their own condition;
- Improve the patient experience of obtaining GFFs on prescription by reducing the number of visits needed to GP surgeries;
- Provide appropriate clinical monitoring for patients directly affected including dietetic intervention and annual pharmacy health check;
- Provide more systematic nationally consistent management of patient needs;
- Allow eligible and qualifying patients access to staple Gluten Free Food to access a convenient service customised to their needs which is also cost effective for NHS Scotland
- Assist through collaborative working the better management of the demand on the time of all members of the primary care team involved in providing this service to patients
- Remove the need for a GP to be involved in issuing multiple gluten free prescriptions once he/she has determined the unit allocation and the patient has registered with a pharmacy
- Reduce the incidence of out of pocket expenses incurred as a consequence of community pharmacy dispensing of individual prescriptions for gluten free foods written by GPs.

2. Service Description

2.1 GFF Service allows eligible and qualifying individuals, who are deemed by their GP as likely to benefit from the service, to register with and use their community pharmacy as the first port of call for the consultation about and dispensing of GFF items, instead of having to request a prescription from their GP for each dispensing. The pharmacist advises, dispenses or refers the patient according to their needs.

2.2 The service is available to any eligible and qualifying person (see section 3.1.2 below).

2.3 The initial consultation and all subsequent health checks must be provided by the pharmacist in person.

2.4 Patients should be directed to support groups or health professionals and should be able to obtain appropriate information about coeliac disease or dermatitis herpetiformis and its management from the pharmacy.

3. Service Outline

3.1 GFF Service Registration and Withdrawal

3.1.1 Qualifying individuals who are eligible for GFF Service can register with an opting-in community pharmacy of their choice to receive GFF items.

3.1.2 The following persons qualify to register for the service:

- Patients diagnosed by their GP as having coeliac disease [or dermatitis herpetiformis] and who would benefit clinically from having access to the GFF service and otherwise would be eligible for a prescription for GFF items written directly by their GP;

3.1.3 Qualifying persons are currently **eligible** to register for the service if they are:

- registered with a Scottish GP practice, other than a person normally resident in a care home,

3.1.4 It should be noted that some patients instead of registering for the service may wish to continue to receive prescriptions from their GP. Non eligible persons by virtue of being normally resident in a care home will continue to receive prescriptions from their GP as at present.

3.1.5 The following persons are **not eligible** to register for the service:

- persons who are not included in the list of eligible persons above;
- persons not registered with a Scottish GP practice;
- those living in a care home; and
- temporary residents;

3.1.6 Individuals can only register with one pharmacy.

3.1.7 During the initial trial period to facilitate the review of the trial an individual registering with a pharmacy for the service should not normally transfer their registration between pharmacies.

3.1.8 The pharmacist registers a person after they present their referral from GP or dietician acting on the GPs behalf. This form must be signed by the GP or dietician. The patient should sign this together with the pharmacist to say that the patient is registering in that pharmacy for the service. The pharmacist should then create a PCR record for the patient.

3.1.9 Registration is either done in advance of requiring to use the service or at the time when the service is first required. Pharmacists must confirm a person is eligible for GFF Service by checking the person's referral letter from the GP/dietician. A

person may not be registered or receive any dispensed GFF items until the appropriate GP referral letter is received, and signed by all relevant parties.

3.1.10 A new registration form signed by the GP will be required if there is a change in units required. (For example change with age, pregnancy.)

3.1.11 Individuals can choose to withdraw from GFF Service at any point. In addition, pharmacists can withdraw an individual; this might be due to, for example, a change in their eligibility or other exceptional circumstances such as suspected misuse of the service. Pharmacists should always check with any newly registering patient that they are not already registered with another pharmacy contractor for GFF Service and if they find that to be the case to advise the patient that they may only access the service during the trial period from the originally chosen pharmacy contractor. The exception to this would be if the patient had moved house during the trial period and could no longer readily visit the originally chosen pharmacy.

3.1.12 National and local publicity initiatives and information leaflets prepared by the Scottish Government are used to raise public awareness of the service.

3.2 GFF Consultation

3.2.1 At the initial consultation all qualifying patients eligible for the service must have appropriate referral from the GP or dietician specifying the number of units that they are entitled to per month. The GP must sign the referral form. The pharmacist should then:

- ask the patient to sign the relevant section on the referral form together with the pharmacist to indicate that they have been registered for the service. The referral forms should be kept for payment verification purposes
- fill in the appropriate PCR record for the patient and consider the most appropriate course/s of action, the counselling and advice needs and any requirements for follow up or referral. The pharmacy annual health check should be **completed at registration** then annually
- help the patient select the most appropriate products. Pharmacy will make agreements with the individual patients as to the best way for their orders to be presented. Orders will then be checked by the community pharmacy to ensure that patients have not exceeded their monthly unit entitlement before processing the orders. Initially this will be via handwritten CPUS forms.
- Agreements will be made with patients regarding how best to contact them in a timely manner following the delivery to pharmacy of their products. This is especially important with fresh products to prevent waste. Details of patients' contacts will be kept on the PCR. Patients should be told that products cannot be reordered if they fail to collect their orders.
- A record of all supplies of gluten-free foods made using CPUS forms is required for the duration of the trial period. A summary of the type and

quantity of gluten-free food is required for each patient to demonstrate that fulfilment of the maximum monthly unit allocation has not been exceeded.

- Pharmacists are required to document the care provided to patients using the PCR.
- Direct access service will be available to patients during all contracted hours.

4. Prescribable Items

4.1 NHS Scotland has adapted the Gluten Free Prescribed Products List produced by Coeliac UK, in so far as this is consistent with ACBS advice, to enable management of the resources assigned to this service. NHS Scotland will attribute a dietary score as a unit to each product. NHS Boards may choose to select a range of products from the Formulary to meet the local needs of patients and enable local arrangements to be made. The patient's dietary assessment will enable an entitlement score (units) to be assigned to each patient based on their clinical and nutritional need. Patients may order any product from the Formulary in line with the local formulary and directions, up to the number of allocated monthly units assigned to them. Patients requiring additional products or products not contained within the local formulary should be advised that it is possible to purchase these products from the pharmacy or local supermarket.

4.2 The Gluten Free Prescribed Products List may be transposed into a local Board level formulary at individual product level to optimise product suitability for patients and cost effectiveness for the Board concerned.

4.3 Pharmacists should prescribe in line with both national and local NHS prescribing policy and guidance.

4.4 GFF service is subject to the same prescribing support as other clinical services.

5. Administration, record keeping and audit

5.1 The patient referral form indicating eligibility for the GFF APS and the number of units they are entitled to per month should be retained by the pharmacist and be used to record the patient's registration on the GFF Service as evidenced by:

- the signature of the patient; and
- the signature of the pharmacist.

5.2 A PCR record should be used for each person. A person may already be registered for the Chronic Medication Service (CMS) and thus have a PCR record whereas others may not and a new PCR may therefore be required. This should be used to record the patient assessment questions on an annual basis after the initial registration date.

5.3 Where appropriate, this information is also annotated into the patient's medication record on the pharmacy patient medication record system.

5.4 The pharmacist must submit the patient's CHI number and GF products supplied on the CPUS form so that the service can be evaluated. Forms without CHI will NOT be reimbursed.

6. Remuneration and reimbursement

6.1 The pharmacy contractor is remunerated during the trial period to 31 March 2015 for providing the GFF Service on availability for service basis as determined by the Drug Tariff.

6.2 If a pharmacy contractor decides that after initially contracting to provide the service they no longer wish to participate in the GFF Service they must notify the Health Board and remuneration funding will be withdrawn for this service from that contractor from the date of their withdrawal.

6.2 The pharmacy contractor is reimbursed for any product from the local formulary supplied at the reimbursement price set in the Drug Tariff by the Health Board concerned.

7. Training and preparing staff

7.1 The pharmacist providing the service must practise within their own competency.

7.2 The pharmacist providing the service must be aware of and operate within the national service specifications and local formulary guidelines.

7.3 Prepare staff

7.3.1 The scope of the direct access service will be set out in a NHS Scotland Service Implementation Pack called - Gluten-Free Food Service Implementation and Support Pack and this will be available through NHS Education for Scotland (NES). A copy will be posted to each community pharmacy and will be available on the NES website from December 2013. Pharmacy contractors taking part in the GFF service should refer to this Implementation and Support Pack when training staff, but are free to develop their own standard operating procedures to deliver the service in their own pharmacy. It is a requirement that locum staff used by the opting-in contractor are also competent to provide the service so that a seamless approach to care is experienced by the patient.

7.3.2 Agreement forms are required to be completed and returned to NHS Boards to ensure that staff are able and willing to participate in the GFF service. By returning the completed agreement forms contractors will have acknowledged that their staff have completed the Implementation and Support Pack and are competent to operate the service. Each pharmacy contractor will designate a named pharmacist(s) to be responsible for the on-going management and delivery of the service.

7.3.3 A training webcast (recording) of the Implementation and Support Pack will be available in December 2013 and NES regional training events will be run in January 2014.

8. Useful references

Link to NES website to access Implementation and Support Pack
www.NES.scot.nhs.uk

Link to webcast (recording) <http://www.neswebinars.co.uk/login.aspx>

To access this webcast you will need to request a password if you have not previously taken part in any webinar training.

Annex C

Gluten-Free Food Service

Patient Registration Form

GPs please complete and sign this part of the form and allow patients to take it to the pharmacy of their choice.

Patient's full name	Male/Female
Patient's CHI number	
Address	Patient's GP/ Surgery
Postcode	
Date of birth	Patients Contact telephone no. and /or e mail address
Condition Coeliac Disease/Dermatitis Herpetiformis	Carer Details (if appropriate)

The above patient should receive the following GFFS units per month.....(in figures).....(in words). Please see Coeliac UK recommended allocated units (<http://www.coeliac.org.uk>).

I have/have not (*please delete*) given prescriptions for one months supply of products.
I will no longer supply GFF for this patient from...../...../..... (date).

GP's signature.....Date.....
GP Name.....GMC no.....

Pharmacists please complete and sign this part of the form.

Registration date	
Patient Medication Record (PMR) completed Yes/no	Name and address of Pharmacy
Pharmacy Coeliac Annual Assessment required Yes/no	

Pharmacist's declaration I declare that the information I have given on this form is correct and complete.

Pharmacist's signature.....Date.....
Contractor's Code.....Pharmacy Stamp

Patients please complete and sign this part of the form.

I agree to obtain my gluten-free foods from the above pharmacy as detailed.

Patient's signature.....Date.....

FORMAT OF DECLARATION TO BE MADE BY COMMUNITY PHARMACY CONTRACTORS OPTING-IN TO THE TRIAL ARRANGEMENTS

Declaration

I declare that the information I shall provide to the Health Board and Practitioners' Services Division on behalf of the Health Board relating to the registration of patients for the Gluten Free Additional Pharmaceutical Service and reimbursement for any items dispensed under the trial will be correct and complete and I understand that if it is not, action may be taken against me. I acknowledge that my claims will be authenticated from appropriate records, and that payment will be made to my Pharmacy, which will be subject to Payment Verification. Where Practitioners' Services Division is unable to obtain authentication, I acknowledge that the onus is on me to provide documentary evidence to support all claims.

Pharmacist's signature..... Date.....

Contractor's Code..... Pharmacy Stamp