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STATUTORY INSTRUMENTS

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**2018 No. 1134**

**NATIONAL HEALTH SERVICE, ENGLAND**

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

<i>Made</i>	- - - -	<i>1st November 2018</i>
<i>Laid before Parliament</i>		<i>6th November 2018</i>
<i>Coming into force</i>	- -	<i>4th December 2018</i>

The Secretary of State for Health and Social Care makes the following Regulations in exercise of the powers conferred by sections 88 and 272(7) and (8) of the National Health Service Act 2006<sup>(1)</sup>.

**Citation and commencement**

1. These Regulations may be cited as the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2018 and come into force on 4th December 2018.

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

2.—(1) The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004<sup>(2)</sup> are amended as follows.

(2) For regulation 2 substitute—

**“Drugs, medicines and other substances that may not be ordered**

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

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

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<sup>(1)</sup> 2006 c. 41.

<sup>(2)</sup> S.I. 2004/629; as amended by S.I. 2004/1625 and 3215, 2009/2230, 2010/2389, 2011/680 and 1043, 2013/363 and 2194 and 2015/1862.

- (2) But—
  - (a) paragraph (1)(b) does not apply to gluten-free bread or a gluten-free food mix;
  - (b) paragraph (1)(c) does not apply to very low gluten bread or a very low gluten food mix.
- (3) For the purposes of this regulation—
  - (a) a food is gluten-free if the food, as sold to the final consumer—
    - (i) contains no more than 20mg/kg of gluten, and
    - (ii) where it contains oats has been specially produced, prepared and or processed in a way to avoid contamination by wheat, rye, barley or their crossbred varieties;
  - (b) a food is very low gluten if the food, as sold to the final consumer, contains no more than 100mg/kg of gluten and consists of, or contains, one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been specially processed to reduce the gluten content, and where it contains oats—
    - (i) it has been specially produced, prepared or processed in a way to avoid contamination by wheat, rye, barley or their crossbred varieties, and
    - (ii) the gluten content of the oats does not exceed 20mg/kg.
- (4) In this regulation—
  - “food mix” means a mixture of two or more ingredients which is to be—
    - (a) combined with any one or more additional ingredients; and
    - (b) baked or otherwise cooked;
  - “gluten” means a protein fraction from wheat, rye, barley, oats or their crossbred varieties and derivatives, which is insoluble in water and 0.5 M sodium chloride solution.”.
- (3) In Schedule 1 (drugs, medicines and other substances not to be ordered under a general medical services contract) omit the entries for—
  - Appleford’s Gluten-Free Rice Cakes;
  - Clara’s Kitchen Gluten-Free Porridge;
  - Ener-G Gluten-free and Soya-free Macaroon Cookies;
  - Ener-G Gluten-free Rice Peanut-Butter Cookies;
  - Ener-G Gluten-free Rice Walnut Cookies;
  - Glutafin Gluten-Free Chocolate Chip Cookies;
  - Glutafin Gluten-Free Custard Cream Biscuits;
  - Glutafin Gluten-Free Gingernut Cookies;
  - Glutafin Gluten-Free Milk Chocolate Biscuits;
  - Glutafin Gluten-Free Milk Chocolate Digestive Biscuits;
  - Glutafin Gluten-Free Shortcake Biscuits;
  - Glutano Gluten-Free Chocolate Hazelnut Wafer Bar;
  - Glutano Gluten-Free Muesli;
  - Glutano Gluten-Free Pretzel;
  - Glutano Gluten-Free Wafer;
  - Glutano Gluten-Free Wafer, Cream Filled;
  - Gratis Gluten-Free Tricolour Pasta;

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

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

1st November 2018

*O'Shaughnessy*  
Parliamentary Under-Secretary of State,  
Department of Health and Social Care

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 (“the 2004 Regulations”) to restrict the circumstances in which gluten-free foods and very low gluten foods may be ordered on prescription under general medical services contracts.

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

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

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

An impact assessment relating to this instrument has been prepared and copies can be obtained from the Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU. It is also available alongside this instrument on [www.legislation.gov.uk](http://www.legislation.gov.uk).