
STATUTORY INSTRUMENTS

2004 No. 629

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

Citation, commencement and application

1.—(1) These regulations may be cited as the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 and shall come into force on 1st April 2004.

(2) These Regulations apply to England only.

[^{F1}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.

(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.]

Changes to legislation: There are outstanding changes not yet made by the legislation.gov.uk editorial team to National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004. Any changes that have already been made by the team appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

Textual Amendments

F1 Reg. 2 substituted (4.12.2018) by [The National Health Service \(General Medical Services Contracts\) \(Prescription of Drugs etc.\) \(Amendment\) Regulations 2018 \(S.I. 2018/1134\)](#), regs. 1, **2(2)**

Drugs, medicines and other substances that may be ordered only in certain circumstances

3. A drug, medicine or other substance specified in an entry in column 1 of Schedule 2 may not be ordered for a patient in the provision of medical services under a general medical services contract unless—

- (a) that patient is a person of a description mentioned in column 2 of that entry; and
- (b) that drug, medicine or other substance is prescribed for that patient only for the purpose specified in column 3 of that entry.

Signed by authority of the Secretary of State

John Hutton
Minister of State,
Department of Health

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Changes and effects yet to be applied to :

- Sch. 2 words inserted by [S.I. 2019/777 reg. 9\(2\)\(a\)\(i\)](#) (This amendment not applied to legislation.gov.uk. Reg. 9 substituted immediately before IP completion day by S.I. 2020/1348, regs. 1, 8)
- Sch. 2 words inserted by [S.I. 2024/728 reg. 2\(2\)\(a\)](#)
- Sch. 2 words inserted by [S.I. 2024/728 reg. 2\(2\)\(b\)](#)
- Sch. 2 words inserted by [S.I. 2024/728 reg. 2\(2\)\(c\)](#)
- Sch. 2 words inserted by [S.I. 2024/728 reg. 2\(3\)](#)
- Sch. 2 words substituted by [S.I. 2019/777 reg. 9\(2\)\(a\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. Reg. 9 substituted immediately before IP completion day by S.I. 2020/1348, regs. 1, 8)