

EXPLANATORY MEMORANDUM TO
THE NATIONAL HEALTH SERVICE (GENERAL MEDICAL SERVICES
CONTRACTS) (PRESCRIPTION OF DRUGS ETC.) (AMENDMENT)
REGULATIONS 2004

2004 No.3215

1 This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2 Description

2.1 This instrument reflects guidance from the National Institute for Clinical Excellence (NICE) specifying the circumstances and categories of patients for whom the treatment for flu should be available on the NHS.

2.2 Oseltamivir (Tamiflu) is used to treat influenza and post-exposure prophylaxis. NICE guidance issued in 2003 recommended that Oseltamivir should be available on NHS prescription to 'at risk' groups such as the elderly and those with severe asthma and respiratory problems.

2.3 Zanamivir (Relenza) is used to treat influenza. The same NICE guidance recommended that Zanamivir should be available on the NHS to the same 'at risk' patients.

2.4 This S.I. gives statutory effect to the NICE recommendations.

3 Matters of special interest to the Joint Committee on Statutory Instruments.

3.1 None

4 Legislative Background

4.1 This SI is an amendment to Schedule 2 to the National Health Service (General Medical Services Contracts)(Prescription of Drugs etc) Regulations 2004 ("the Drugs Regulations"). Schedule 2 is a list of drugs which GPs may prescribe under a general medical services contract only in specified circumstances, and/or for specified patient groups. The drugs which are included on this list are published by the Stationery Office in Part XVIII of the Drug Tariff. Please see part 7, Policy Background for further information about the origins of this policy decision.

4.2 Paragraph 42(2) of Schedule 6 to the National Health Service (General Medical Services Contracts) Regulations 2004 provides that, where a drug is included in Schedule 2 to the Drugs Regulations, a GP will nevertheless be able to prescribe it privately to his NHS patients outside the circumstances set out in Schedule 2 provided that he does not charge them for the prescription.

4.3 Although the Drugs Regulations (and these amending regulations) only deal with prescribing for the purposes of general medical services (GMS)

contracts, the same prescribing restrictions are applied to other types of NHS primary medical services contracts by terms in those contracts which refer to the Drugs Regulations.

5 Extent

5.1 This instrument applies to England only.

6 European Convention on Human Rights

6.1 Not applicable

7 Policy Background

7.1 The policy objective of this SI is to make a clear distinction as to what is available on the NHS and what is not.

7.2 In February 2003, NICE issued guidance to the NHS recommending that the pharmaceutical products subject to this SI (Tamiflu and Relenza) should be prescribed only for defined "at risk" groups, principally the elderly and those with severe asthma/respiratory problems. Tamiflu is also licensed for the treatment of children.

7.3 In September 2003, NICE issued further guidance to the NHS recommending that Tamiflu also be used for post-exposure prophylaxis for influenza in the same 'at-risk' groups.

7.4 'At-risk' people are defined as those who are in at least one of the following groups. People who:

- have chronic respiratory disease (including chronic obstructive pulmonary disease and asthma)
- have significant cardiovascular disease (excluding people with hypertension only)
- have chronic renal disease
- are immunocompromised
- have diabetes mellitus
- are aged 65 years or older.

7.5 Since NICE guidance is not legally binding, this left the position of doctors unclear when patients asked them to prescribe these drugs outside of the circumstances covered by the NICE recommendations. This S.I makes clear that:

(a) Tamiflu and Relenza will be available on the NHS only in the circumstances recommended by NICE; and

(b) Where they judge it to be clinically appropriate, doctors can issue private prescriptions to their NHS patients for these drugs provided that they do not charge them for the prescription.

8 Impact

- 8.1 A Regulatory Impact Assessment has not been prepared for this instrument as it has no impact on business, charities or voluntary bodies

Contact

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