EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (GENERAL MEDICAL SERVICES CONTRACTS) (PRESCRIPTION OF DRUGS ETC.) (AMENDMENT) REGULATIONS 2010

2010 No. 2389

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

2. Purpose of the instrument

2.1 These Regulations amend Schedule 2 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 ("the 2004 Regulations") to widen the description of patients for whom a general medical practitioner may order the two influenza treatments , namely Oseltamivir (Tamiflu) and Zanamivir (Relenza) under the terms of their general medical services contract. The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2010 ("the 2010 Regulations") also amends the conditions which must be met in relation to the patients falling within the widened description of patients.

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

3.1 None

4. Legislative Context

4.1 Regulation 3 of the 2004 Regulations, provides that a general medical practitioner under the terms of his general medical services contract may not order specified drugs, medicines and other substances which are listed in column 1 of Schedule 2 to those Regulations unless a patient falls within a specified description and the drug, medicine or other substance is prescribed for a specified purpose. Column 2 of Schedule 2 describes the patients and column 3 specifies the purpose for which the drug, medicine or substance is prescribed.

4.2 The provisions relating to the two influenza treatments, namely Tamiflu and Relenza in the 2004 Regulations are outdated as a consequence of medical developments regarding influenza and the related expert advice. There have also been changes to the licensing conditions of Tamiflu and Relenza which are reflected in the relevant guidance from the National Institute for Health and Clinical Excellence and which are also reflected the 2010 Regulations. The 2010 Regulations widen the description of patients in column 2 who should be eligible under the NHS to receive the two influenza drugs. Also widened is the description of patients who have particular health condition and fall within an at-risk category – a new category of "at clinical risk" is inserted into the 2004 Regulations and is defined. The conditions which must be met before either of the influenza drugs in column 2 can be ordered is also amended to reflect the way in which general medical practitioners are informed that influenza is circulating in the community; and the time frame within which

treatment is to commence is amended to reflect the licensing conditions under which these drugs are recommended for use.

4.3 Without these amendments, general medical practitioners would be in breach of their contractual terms of services if the drugs were ordered for those patients who are not included in the description in column 2.

5. Territorial Extent and Application

5.1 This instrument applies to England.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

What is being done and why.

7.1 The policy objective of the 2004 Regulations is to ensure that patients who are at risk of contracting influenza, who are considered likely to benefit from treatment with Tamiflu or Relenza if they become ill with influenza, can receive these treatments on the NHS in certain circumstances. People who do not fall within the described group can obtain private prescriptions for these treatments – but not on the NHS.

7.2 The list of persons who are at risk is identified by the Chief Medical Officer in relation to vaccination and this forms the basis of who is targeted to receive prophylaxis or treatment with the influenza drugs - Tamiflu and Relenza. The Chief Medical Officer regularly reviews and updates the groups he believes are at risk from the influenza virus.

7.3 The list of description of people who are at risk and the conditions in the 2004 Regulations have not been reviewed and amended for a number of years. The provisions have become outdated and this was highlighted particularly as a consequence of the 2009 swine influenza pandemic. In the 2009 swine influenza pandemic, pregnant women and children under the age of 5 were found to be at risk from developing serious complications as a result of contracting swine influenza. The treatments for swine influenza, Tamiflu and Relenza, were available during the pandemic through emergency measures. However, in normal circumstances these treatments would only be available on the NHS if a patient fell within one of the “at risk” groups set out in Schedule 2 of 2004 Regulations. The amendments are required to ensure that general medical practitioners may order the two drugs for patients in particular circumstances which accords with expert advice without breaching their contractual terms of service.

7.4 The 2010 Regulations add people with chronic liver disease and people with chronic neurological disease to the list of “at clinical risk” people eligible to receive these treatments on the NHS in certain circumstances. These two groups have been added on the basis of expert advice from the Joint Committee on Vaccines and

Immunisations which was provided to the Chief Medical Officer and included in his annual letter outlining the clinical at risk groups.

7.5 The 2010 Regulations also enable pregnant women to receive the treatments. The World Health Organisation have advised that swine influenza will form part of the 2010/11 seasonal influenza. Experience from the swine influenza pandemic in 2009/10 has shown that pregnant women are more likely to suffer serious complications if they become ill with the virus. Based on this advice, and that of the Joint Committee on Vaccines and Immunisations, the Chief Medical Officer included pregnant women in the "at risk" groups and the 2010 Regulations reflect this.

7.6 Since the 2004 Regulations were made there have been changes to the ways in which general medical practitioners are informed that the influenza virus is circulating in the community - the 2010 Regulations reflect this.

7.7 The remaining changes, included in the 2010 Regulations, reflect revisions to the licensing conditions of the treatments as outlined in the Summary of Product Characteristics (SPC) for the two individual products. These changes relate to the age at which children can be prescribed the treatments and the time at which the patient can start therapy for the individual products. The 2010 Regulations reflect these changes and also ensure consistency with the current National Institute for Health and Clinical Excellence's guidance on influenza - Technology Appraisal Guidance 168 on Treatment and Technology Appraisal Guidance 158 on prophylaxis.

Consolidation

7.8 The Department has no immediate plans to consolidate the proposed amendments to the National Health Service(General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2010. The Department believes that the amendments primarily impact on general medical practitioners who have a general medical services contract, and other relevant prescribers. The Department considers it more appropriate to inform all of the relevant healthcare professionals about these amendments through the Departmental Publications *The Week* and the *GP Bulletin*, and evaluate if further amendments or consolidation is required in 12 months.

8. Consultation outcome

8.1 The Department of Health undertook a specific engagement exercise for a period of four weeks, rather than a full 3-month public consultation exercise. The consultation was directly with the manufacturers of the two products – GlaxoSmithKline and Roche - and with the General Practitioners Committee of the British Medical Association. The consultation included full details of the proposals and consultees had an opportunity to comment on the finalising the 2010 Regulations as well.

8.2 The consultees were given the opportunity of a meeting to discuss any concerns, but none requested this. All consultees confirmed they were content with the Department's proposals. The General Practitioners Committee of the British Medical Association commented there should be some statements for the public and professionals about these changes. The Department intends to address this by

sending out a direct communication to all GPs through the *GP Bulletin* and more widely to the healthcare community through other Department of Health publications advising of the change in legislation, with details of the additional categories of patients and the conditions which must be met before the two drugs may be ordered.

8.3 The Department undertook a shortened, specific engagement exercise with the three consultees to make sure that general medical practitioners may order the two drugs for patients in particular circumstances which accords with expert advice without breaching their contractual terms of service in time for the forthcoming influenza season. With the particular concerns as to the welfare of pregnant women, the Department wanted to ensure the availability of the products for this influenza season. A three-month consultation would have meant that any changes could not become effective until nearer to December resulting in a delay in the treatments being available through general medical practitioners who provide NHS primary medical services under a general medical services contract.

9. Guidance

9.1 The Department of Health intends to issue notification of these changes through the Department's publications, *The Week* and the *GP Bulletin*, with a link to the DH website in October.

10. Impact

10.1 The Department of Health do not foresee any impact on business, charities or voluntary bodies.

10.2 The Department estimate there will be a very small impact on the public sector, in terms of an increase in the number of consultations with general medical practitioners.

10.3 An Equality Impact Screening Assessment was undertaken and concluded that a negative impact is unlikely.

10.4 An Impact Assessment has not been prepared for this instrument. The Department has estimated, based on records received on individuals eligible for influenza vaccines for 2009, there are 580,000 people with chronic liver disease and people with chronic neurological disease. The estimates for pregnant women are based on the number of births and abortions per year - approximately 550,000. Taking these two figures together, an additional 1.1 million people, in England, will now be included in the category of patients for whom the drug can be ordered.

10.5 The new category of patients will be invited, as part of the seasonal influenza campaign, to receive the influenza vaccination and should be effectively protected from the illness. However, of the additional 1.1 million "at risk" people, based on 2009 prescribing data from the NHS Information Centre, it is estimated 0.16% will go on to have the antiviral treatments Tamiflu or Relenza prescribed. This totals an extra 1,800 extra prescriptions and associated consultations with general medical practitioners or other relevant prescribers.

10.6 In terms of the impact on general medical practitioners and based on data from the NHS Information Centre, the Department of Health estimate an average of two extra consultations per surgery per year. This is a minute percentage of the 36,452 consultations an average GP surgery undertakes per year.

11. Regulating small business

11.1 The statutory instrument does not apply to small business.

12. Monitoring & review

12.1 The Department will monitor and review the seasonal influenza programme and the legislation in light of the advice of the Joint Committee on Vaccination and Immunisation for the 2011/2012 season. It will also monitor the prescribing data for the numbers of prescriptions of Tamiflu and Relenza for the 2010/11 influenza season. As such the Department will consider in 12 months time whether the 2004 Regulations may need review and if necessary amendment.

13. Contact

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email: natalie.cullen@dh.gsi.gov.uk can answer any queries regarding the instrument.