EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (GENERAL MEDICAL SERVICES CONTRACTS) (PRESCRIPTION OF DRUGS ETC.) (AMENDMENT) REGULATIONS 2011

2011 No. 680

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

2. Purpose of the instrument

2.1 The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2011 ("the 2011Regulations") amend Schedule 2 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) 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.

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 Amendments are required to the provisions relating to the two influenza drugs, (Tamiflu and Relenza) in the 2004 Regulations because in the 2010/11 influenza season, some otherwise healthy people have become seriously ill with H1N1 influenza ("swine flu"). The 2011 Regulations widen the description of patients in column 2 who should be eligible under the NHS to receive the two influenza drugs. A new category of patients who are "at risk of developing medical complications" is added.

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 ("CMO") 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 CMO regularly reviews and updates the groups she believes are at risk from the influenza virus, taking account of relevant guidance from the Joint Committee on Vaccination and Immunisation (JCVI).

7.3 The list of description of people who are at risk and the conditions in the 2004 Regulations were reviewed in 2010 to add amongst others, pregnant women. These changes were made as a consequence of the experience of the 2009 swine flu pandemic – where pregnant women were found more likely to become seriously ill with swine flu. Swine flu (H1N1(2009)) is expected to circulate every winter for the foreseeable future and is now regarded as one of the strains that are collectively described as seasonal influenza. Swine flu is one of the predominant strains in the current influenza season.

7.4 Experience from the influenza season in 2010/11 has shown that some people who are not in any of the current "at clinical risk" categories and who have no particular or identifiable underlying conditions have become seriously ill with influenza. It is not possible to define this category of patient as anything other than "at risk of developing medical complications" if they become ill with the virus as the conditions which must be met before the drugs are prescribed will change in response to changing expert advice on the particular pathology of each outbreak of the virus. Prescribing decisions will therefore be informed by guidance communicated to GPs by the CMO, which itself may fluctuate depending on circumstances.

7.5 Data from the Health Protection Agency has shown that for the 2010/11 influenza season, up to 2 March 2011, 539 fatal influenza cases from across the UK have been reported to the HPA. Of 460 fatal cases with available information, 134 (29%) were not in the current "at medical risk" groups.

7.6 To address this problem, the CMO issued advice (Gateway Ref: 15338)[1] on 21 December that the drugs available to treat influenza, Tamiflu and Relenza, should be more widely available. She recommended that the regulatory restrictions should be amended to allow general medical practitioners to exercise their clinical discretion so that any patient who their GP feels is at risk of developing complications from influenza may receive these treatments on the NHS. In the meantime, the CMO advised PCTs to take no action to instigate enquiries into general medical practitioners prescribing in these circumstances.

7.7 The 2011 amendment Regulations are required to ensure that general medical practitioners may order the two drugs for patients in a new category of patient "at risk of developing medical complications" without breaching their contractual terms of service.

- **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 2011. 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*, the *Chemist and Druggist* 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 with:

- the manufacturers of the two products – GlaxoSmithKline and Roche :
- the General Practitioners Committee of the British Medical Association;
- the Royal College of General Practitioners; and
- the Pharmaceutical Services Negotiating Committee.

8.2 The consultation was for a period of four weeks, rather than a full 3-month public consultation exercise. The Department undertook a shortened consultation exercise because the above consultees are the ones directly affected. In addition they had recently been involved in a very similar consultation on amendments to the "at clinical risk" groups in November 2010. The interim measures outlined in the CMO advice - Gateway Ref .15338 (paragraph 7.6 above) do not accord with the provisions of the 2010 Regulations and urgent action is required to formalise the statutory provisions. A three-month consultation would have delayed formal changes which allow the drugs to be prescribed by general medical practitioners who provide NHS primary medical services under a general medical services contract.

8.3 The consultation included full details of the proposals and consultees had an opportunity to comment on finalising the 2011 Regulations as well. The consultees were given advance notice of the Department's intention to consult in December. To ensure they were not disadvantaged, they were given the opportunity of a meeting to discuss any

[1] http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_123096

concerns, but none requested this. All consultees confirmed they were content with the Department's proposals. In particular, the RCGP responded that they "welcome this proposed change"and the GPC at the BMA said they were happy with the proposed changes.

9. Guidance

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

10. Impact

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

10.2 The Department estimate that any impact on the public sector will be related to the numbers of people ill with influenza, rather than as a result of increasing the availability of antivirals. We do not estimate that increasing the availability of the antivirals will have any impact on the numbers of patients seeking 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 NHS Information Centre prescribing data for England for December 2010, the first month in which the antivirals were more widely available, indicates a ten-fold increase in prescriptions, compared to 2008. The total costs of antiviral prescriptions are rounded up to £22,000 in 2008 and to £220,000 in 2010. The 2009 data cannot be used as a true reflection of prescribing of antivirals as large numbers were issued through the emergency pandemic measures, rather than by prescription.

10.5 The Department estimates that in future influenza seasons, as more people have become immune to swine flu, the numbers of antivirals prescribed will decrease (from the December 2010 figure). Based on this early prescription data, we estimate additional prescribing costs of about £100,000 per month for the new category of patient "at risk of developing medical complications". The Health Protection Agency data from the past 19 years' of influenza seasons indicates that the most frequent range for a influenza season is between 6 and 10 weeks. Based on this we estimate additional costs of £200,000 per year of the £8 billion a year spend on the primary care drugs bill.

10.6 The Department believes this additional cost on the primary care drugs bill will provide benefit to the secondary care sector, who without this early intervention may incur significant costs relating to treating patients in intensive care units.

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 and 2012/13 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.