# EXPLANATORY MEMORANDUM TO

# THE NATIONAL HEALTH SERVICE (GENERAL MEDICAL SERVICES CONTRACTS) (PRESCRIPTION OF DRUGS ETC) (AMENDMENT) REGULATIONS 2013

## 2013 No. 2194

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

This memorandum contains information for the Joint Committee on Statutory Instruments

## 2. Purpose of the instrument

2.1 The Department of Health (" the Department") has become aware of some legal uncertainty relating to the operation of the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004 (S.I.2004/629), ("the Regulations"). The Regulations currently restrict NHS prescribing of drugs for the treatment of erectile dysfunction (ED). Since the Regulations were originally introduced, some of the ED drugs listed in Schedule 2 to the Regulations have received alternative licenses for the treatment of medical conditions other than those specified in Schedule 2. There is a risk that the Regulations could therefore be interpreted so as to prohibit those ED drugs from being prescribed for the treatment of these alternative medical conditions. This is not consistent with the original policy intention behind the Regulations. The proposed changes to be made by the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) (Amendment) Regulations 2013 ("the Amendment Regulations") are intended to clarify the intended position regarding the availability of the ED treatments specified in Schedule 2 to the Regulations when they are prescribed on the NHS for the treatment of other medical conditions.

2.2 We expect the new instrument to ensure treatments for benign prostatic hyperplasia and pulmonary arterial hypertension can be prescribed in primary care for NHS patients.

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

3.1 A shortened and specific consultation exercise of targeted representative interests was conducted for a period of two weeks because this instrument makes a technical change which clarifies the intention in the Regulations; it does not alter the policy.

3.2 In addition, the Department considers that the proposed changes need to be introduced as soon as possible in order to resolve the current legal uncertainty in the Regulations both for manufacturers and prescribers of the relevant ED treatments and to ensure continuity of patient care. In order for the changes to come into force from 1st October this year as proposed, the Department considers that it is both appropriate and necessary in this instance to lay the draft Amendment Regulations while Parliament is in recess and for a period of less than the usually expected 28 sitting days.

## 4. Legislative Context

4.1 Regulation 3 of the Regulations, provides that a general medical practitioner, under the terms of a general medical services contract, may not order specified drugs, medicines and other substances which are listed in column 1 of the table in Schedule 2 to the 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 the table in Schedule 2 describes the patients and column 3 of that table specifies the purpose for which the drug, medicine or substance may currently be prescribed.

4.2 The Department considers that the current provisions in Schedule 2 of the Regulations relating to ED treatments have become outdated over time as a consequence of additional (medical) indications having been obtained in relation to the licensing conditions of many of those treatments. The draft Amendment Regulations make provision to amend the entry in the table in Schedule 2 relating to ED treatments so as to clarify that any such drug may also be ordered for any patient for the purpose of treating a medical condition other than erectile dysfunction if it is considered an appropriate treatment for that condition. The scope of the provisions in column 3 of the table in Schedule 2 relating to the purpose for which the ED treatments may be prescribed on the NHS has therefore been widened. In addition, provision is also made to remove the references to the brand names of the chemical products (medicines) specified in column 1 of the table in Schedule 2. This is intended to make it clear that the prescribing restrictions in the Regulations apply to all formulations of the active ingredient in those ED treatments in whatever way they are presented.

4.3 The Department considers that, without these amendments, general medical practitioners would technically be acting in breach of their current contractual terms, albeit in circumstances where the Department would not expect NHS England to seek to impose contractual sanctions, if they prescribed the specified ED treatments to patients who do not suffer from erectile dysfunction for the treatment of another medical condition DH considers that these legal difficulties and, most importantly, the need to ensure that patients get their medicines, mean that it is appropriate to introduce these changes as soon as possible.

## 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 Department has become aware of some legal uncertainty relating to the legislation which restricts the prescription of ED treatments in NHS in primary care. Certain ED treatments are restricted on NHS prescription by virtue of provision in Schedule 2 to the Regulations which currently lists the drugs, medicines and substances that may be ordered in relation to the provision of medical services under a General Medical Services Contract in certain circumstances for persons of prescribed descriptions.

7.2 The Schedule 2 restrictions mean that the listed ED treatments may only be prescribed for men with ED who are identified as suffering from certain medical conditions. Where they are prescribed for persons fulfilling the description set out in Schedule 2, the prescriber has to indicate by endorsing the prescription with the letters 'SLS'. In conjunction, The National Health Service (Pharmaceutical and Local Pharmaceutical Service) Regulations 2013 (S.I. 2013/349) do not provide for an NHS dispenser to dispense a product listed in Schedule 2 to the Regulations, unless the prescription has been endorsed 'SLS' by the prescriber. Prescriptions have to be annotated "SLS" to indicate to the dispenser that the patient falls within these criteria. The SLS marking allows prescriptions to be passed for payment without challenge.

7.3 The ED treatments specified in Schedule 2 to the Regulations were originally restricted in order to curtail NHS spending on what was seen at the time as a "lifestyle" treatment. The intention of the Regulations was to restrict the use of these products for the treatment of ED. However, there is a risk that the Regulations could now be interpreted as prohibiting the prescription of those ED treatments for the treatment of other medical conditions. This is not consistent with the original policy intention.

7.4 Cialis (tadalafil) is one of the restricted ED treatments. It has recently received a license for the treatment of another medical condition - benign prostatic hyperplasia (BPH). In responding to queries from the NHS about whether the prescribing restrictions apply to this condition,

the Department has concluded that, under the current Regulations, the statutory restrictions do apply. This means that the drug cannot be prescribed by general practitioners under a general medical services contract for the treatment of BPH unless a patient meets the criteria set out in the legislation.

7.5 There is also a wider issue relating to prescriptions for the restricted ED treatments which have more than one clinical indication. An example is for the ED treatments Viagra and Cialis, which are also licensed for the treatment of pulmonary arterial hypertension (PAH) under different brand names - Revatio and Adcirca. These alternative brand names do not appear in the list of restricted treatments in Schedule 2 to the Regulations, but the generic names of the product (sildenafil and tadalafil) do. The Department believes that, historically, NHS prescribers have prescribed these treatments under the PAH brand names and the NHS reimbursement process has allowed prescriptions to go unchallenged. The Department does not consider that the Regulations, as currently worded, allow this flexibility. The changes to be made by the draft Amendment Regulations are therefore intended to clarify the current legal irregularity regarding the availability of the ED treatments on the NHS when they are prescribed for the treatment of other medical conditions.

- Consolidation

7.6 The Department has no immediate plans to consolidate the Regulations. The Department considers that the amendments made by the Amendment regulations primarily impact on the prescribing behaviour of general medical practitioners who have a general medical services contract, and other relevant prescribers.

## 8. Consultation outcome

8.1 In view of the technical nature of the change, the Department undertook a consultation with a small number of stakeholder groups – the Association of the British Pharmaceutical Industry, the British Generic Manufacturers Association, the Royal College of General Practitioners, the British Medical Association, the Pharmaceutical Services Negotiating Committee, the Patients Association and National Voices.

8.2 The overall response was positive and organisations were supportive of the changes being made. The Department provided further information to the Patients Association and National Voices to further clarify the reasons for the changes.

## 9. Guidance

9.1 The Department has consulted on these changes directly with a range of relevant stakeholder groups, representing NHS - patients, commissioners, prescribers and dispensers, and manufacturer organisations.

## 10. Impact

10.1 The Department does not envisage any regulatory burden being imposed by the effect of the proposed changes it is making in the Amendment Regulations. This is because they are technical changes intended to clarify the legal position and to enable NHS prescribers to continue to prescribe certain ED treatments without being in breach of their NHS contracts.

10.2 The Department does not envisage any impact on the public sector.

10.3 An Impact Assessment has not been prepared for this instrument. The Department does not envisage any regulatory burden resulting from the proposed amendments as they are technical changes to enable prescribers to prescribe certain treatments without being in breach of their contracts.

## 11. Regulating small business

11.1 The legislation does not apply to small business.

## 12. Monitoring & review

12.1 The Department will separately be consulting later in 2013 on the wider issue of the availability of Sildenafil on the NHS. It will monitor and review any feedback from these amendments as part of that review. The Department considers it unlikely there will be any effect, other than correcting a legal irregularity, from these technical changes.

## 13. Contact

**Natalie Cullen** at the Department of Health Tel: 0113 2546313 or email: Natalie.cullen@dh.gsi.gov.uk can answer any queries regarding the instrument.