EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (GENERAL MEDICAL SERVICES CONTRACTS) (PRESCRIPTION OF DRUGS ETC.) (AMENDMENT) REGULATIONS 2014

2014 No. 1625

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 This instrument amends Schedule 2 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 (S.I. 2004/629) ("the 2004 Regulations") in two ways. It removes the statutory prescribing restrictions for the drugs, generic sildenafil, apomorphine hydrochloride, moxisylyte hydrochloride and thymoxamine hydrochloride for the treatment of erectile dysfunction (ED) and it creates prescribing restrictions for the recently licensed drug, avanafil (brand name Spedra), also for the treatment of ED.

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 the 2004 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 in Schedule 2 currently restricts general practitioner prescribing of a number of treatments for ED, on the grounds of cost to the National Health Service. The Department of Health ("the Department") considers that the current provisions in Schedule 2 have become outdated as a consequence of Viagra losing its patent protection and generic preparations of the medicine, sildenafil, becoming available much more cheaply. The current provisions restrict general medical practitioners from prescribing listed ED treatments, including generic sildenafil. Viagra lost its patent protection in June 2013 in the UK and the manufacturer, Pfizer, no longer has exclusive rights over the active ingredient sildenafil, allowing other manufacturers to market generic sildenafil much more cheaply. In the light of this significant reduction in the cost to the NHS E of this of treatment, the Department now wishes to remove the prescribing restrictions for generic sildenafil.

4.3 A newly licensed ED treatment, avanafil – brand name Spedra - has recently been launched in the UK. As this is a premium priced branded ED treatment, the Department wishes to restrict NHS prescribing of avanafil by including it in Schedule 2.

4.4 The proposed changes to be made by the National Health Service (General Medical Services Contracts) (Prescription of Drugs) (Amendment) Regulations 2014 ("the Amendment Regulations") make provision to amend the entry in the table in Schedule 2 relating to ED treatments to remove the reference to sildenafil, apomorphine hydrochloride, moxisylyte hydrochloride and thymoxamine hydrochloride and to add avanafil. Viagra is also added to the entry to preserve the current prescribing restriction for the branded version of sildenafil. The Department is seeking to make provision to allow unrestricted prescribing of generic sildenafil, according to practitioners' clinical judgement, whilst continuing to restrict other in-patent branded products for the treatment of ED.

5. Territorial Extent and Application

5.1 This instrument applies to England only.

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 prescribing restrictions in England are set out in Schedule 2 to the 2004 Regulations. These Regulations provide that GPs cannot prescribe products listed in Schedule 2 except in certain circumstances, for example, for patients with underlying health conditions causing ED, such as diabetes or prostate cancer. GPs will be in breach of their contractual terms of service if they prescribe the treatments outside of the defined circumstances.

7.2 The European Commission's Transparency Directive (89/105/EEC) ("the Directive") provides the basis of these restrictions. Article 7 of the Directive allows member states to notify the Commission of measures regulating the pricing of medicinal products. One of the UK's notified criteria, criterion 5, sets out that certain medicinal products may be excluded from supply by way of NHS prescription on grounds of cost. Following the rapid reduction in the price of generic sildenafil, the Department is unable to continue to justify restricting it on the grounds of the original notification. The price of generic preparations of Sildenafil has dropped by over 90% of the price of branded Viagra – dropping from £21.27 (according to June 2013 edition of the Drug Tariff) to £1.15 (June 2014 edition of the Drug Tariff) for a 50mg 4 tablet pack. However, the position has not changed for the other in-patent and branded ED treatments and the notification remains valid for these.

7.3 Balancing cost to the NHS and benefits to patients, the Department considers removing the restrictions for generic sildenafil provides the greatest benefit and we do not propose to seek to restrict it under other notifications to the Commission.

7.4 At the same time as we proposed changes for generic sildenafil, a newly licensed ED treatment, (avanafil – brand name Spedra) was launched in the UK. Our rationale for continuing to restrict in-patent and branded ED treatments under criterion 5, Article 7 of the Directive also applies to avanafil and we are adding it to Schedule 2 alongside our other changes. Though avanafil is not as expensive as Viagra, it is significantly more expensive than generic sildenafil and there is a large potential cost to the NHS of having a branded ED treatment freely available on NHS prescription, without any restrictions.

7.5 The changes also remove apomorphine hydrochloride, moxisylyte hydrochloride and thymoxamine hydrochloridefrom the list of restricted ED treatments. Since their original listing in the Regulations, these drugs have lost their patent protection and/or are not licensed for use in ED and it is now not appropriate to continue to restrict them. The patent for ED for apomorphine hydrocholrodie was discontinued in 2006. Moxisylyte hydrochloride and thymoxamine hydrochloride have no extant patent and are not licensed for use in ED. Viagra is also added to the entry to preserve the current prescribing restriction for the branded version of sildenafil

- Consolidation

7.6 The Department has no immediate plans to consolidate the 2004 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 The Department undertook two separate consultation processes - one setting out our proposals to remove the prescribing restrictions for generic sildenafil, apomorphine hydrochloride, moxisylyte hydrochloride and thymoxamine hydrochloride and another about our proposals to restrict the prescribing of avanafil. The Department was informed about the UK launch date for avanafil after the sildenafil consultation had closed so it was not possible to combine the consultations.

8.2 Our consultation '*Proposed changes to NHS availability of erectile dysfunction treatment*' ran for eight weeks (23rd January to 21st March 2014). We engaged with key stakeholders including doctors' groups, drug manufacturers, patients associations, men's health organisations and the other UK health departments.

8.3 We received 87 responses, and 81% of these were in agreement with our proposals to make sildenafil more widely available on NHS prescription. Further detail on the consultation responses submitted is set out in the Department's formal response at:

https://www.gov.uk/government/consultations/nhs-availability-of-erectile-dysfunction-drugs-proposed-changes

8.4 Comments in support of the proposed change focussed on the overall benefits for men's health, the most common response being that the proposals will reduce the number of men seeking unregulated supplies of ED treatments from the internet. Several consultees also commented that the proposals will benefit those men who under the current restrictions are treated at hospital-based clinics, and who as a result of the changes will be able to receive treatment from their own GP.

8.5 Whilst the proposals were overwhelmingly supported, 16 consultees suggested that the proposals could be unfair for those patients who cannot tolerate sildenafil and who do not fall within the category of patients eligible to have an alternative branded ED treatment prescribed by their GP. They suggested that we should relax the restrictions on prescribing of branded in-patent ED treatments to allow them to be prescribed to any patient who has been unable to tolerate sildenafil. This would mean those treatments being available more widely than the current provisions allow.

8.6 The Department has considered this issue very carefully, taking into account the Secretary of State's equality duty and the Secretary of State's duties under section 1 of the National Health Service Act 2006, in particular, the section 1C duty as to reducing inequalities. As our published response to the consultation makes clear, we believe that relaxing prescribing of in-patent branded treatments in this way would incur significant additional costs of up to tens of millions of pounds to the NHS. Continuing to restrict prescribing of these products to patients who meet specific clinical criteria is in line with our existing notification under the Directive. Furthermore, NHS patients who are unable to tolerate sildenafil and who are as a result experiencing serious distress will continue to be able to access in-patent branded ED treatments through NHS specialist services, where clinically appropriate, as the statutory restrictions apply only to prescribing by general medical practitioners. Patients unable to tolerate particular manufacturers generic preparations can discuss this with their GP who may consider if it is appropriate to prescribe another manufacturer's generic preparation.

8.7 Some respondents also felt the Impact Assessment underestimated potential costs to the NHS relating to increased demand for sildenafil. The Department will monitor prescribing data to track spending patterns following the changes.

8.8 The consultation also proposed removing the statutory prescribing restrictions for four ED treatments which were not covered by patent protection or did not have a license for ED. 5 respondents commented that although one of these treatments, alprostadil, has no extant patent the product generally requires special administration by brand and continues to be priced at a premium. On this basis we do not propose to remove the statutory prescribing restrictions for this product.

8.9 The Department undertook a shorter, targeted consultation on proposals for avanafil. The consultation ran for four weeks, from 2nd to 28th April, with a selected 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 (BMA), the Pharmaceutical Services Negotiating Committee and the manufacturers for avanafil, Menarini.

8.10 This consultation received two responses, one from Menarini confirming they are content for the product to be listed and one from the BMA. Whilst the BMA is also content for avanafil to be listed, they have reiterated that they do not agree with the overall principle of ED treatments being restricted. The Impact Assessment provides the basis for the Department's continued restrictions on branded ED treatments on grounds of cost to the NHS and we do not have any plans to review this position at present.

9. Guidance

9.1 NHS England has national responsibility for issuing prescribing guidance. The Department will engage with NHS England to consider whether it is appropriate to develop guidance to support GPs and other prescribers in understanding and applying the regulatory changes. Details of the changes to Regulations will be communicated through the relevant NHS England bulletins.

10. Impact

10.1 A final version of the Impact Assessment (IA) for these changes is available at www.legislation.gov.uk/ukia/2013/240 and is attached as Annex A. The IA demonstrates that the benefits of our proposals outweigh the costs. We believe it is a fair representation of the best available evidence and supports our reasons for change.

11. Regulating small business

11.1 The legislation does not apply to small businesses

12. Monitoring & review

12.1 The Department will monitor the prescribing data for the numbers of prescriptions of erectile dysfunction treatments over the next 24 months. As such the Department will consider in two years whether the 2004 Regulations may require review and if necessary amendment.

13. Contact

Stuart Merritt at the Department of Health [Tel: 0113 2545162/Email: stuart.merritt@dh.gsi.gov.uk] can answer any queries regarding the instrument.