EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (GENERAL MEDICAL SERVICES CONTRACTS) (PRESCRIPTION OF DRUGS ETC.) (AMENDMENT) REGULATIONS 2025

2025 No. 987

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department of Health and Social Care (DHSC), in collaboration with the UK Health Security Agency (UKHSA) and is laid before Parliament by Command of His Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Declaration

2.1 Minister Karin Smyth, Minister of State for Health (Secondary Care) at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

2.2 Helen Lovell, Deputy Director for Medicines Regulation and Prescribing at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Cicely Groom at the Department of Health and Social Care can be contacted by email at the following address with any queries regarding the instrument: prescribingpolicy@dhsc.gov.uk

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

Regarding prescribing of tadalafil and vardenafil

4.1 The instrument amends Schedule 2 to the NHS (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 (the Regulations) to allow generic tadalafil and vardenafil to be prescribed without restrictions on the NHS in primary care.

4.2 The Selected List Scheme (SLS), also called the "conditional list", is set out under Part XVIIIB of the NHS Drug Tariff which reproduces Schedule 2 of the Regulations. The Drug Tariff is a monthly publication produced by NHS Business Services Authority (NHSBSA) on behalf of the Department of Health and Social Care. It outlines the information needed for pharmacy contractors, including reimbursement details, dispensing rules, and fees for NHS services. The Drug Tariff provides a list of drugs and appliances, along with their prices, to ensure consistent reimbursement practices across the NHS in England and Wales.

4.3 The SLS restricts NHS prescribing of certain medicines to specific clinical conditions, originally due to concerns such as high cost or limited effectiveness. Generic tadalafil and vardenafil are included in the SLS but since their patents ended (2017 and 2018

respectively), their prices have significantly decreased, and the original cost-based justification for their inclusion in the SLS no longer applies.

Regarding prescribing of oseltamivir (Tamiflu) and zanamivir (Relenza)

4.4 The amendment will enable oseltamivir and zanamivir to be prescribed and dispensed via standard prescription processes outside of the flu season, improving efficiency of the process the prescribe the antivirals out of season. This amendment reflects improvements in respiratory infection testing since the COVID-19 pandemic, meaning the original rationale for restriction no longer applies.

4.5 The policy context and aims for the two distinct groups of medicines have been developed separately by DHSC and UKHSA and are combined into one Statutory Instrument to make the most efficient use of parliamentary time.

Where does the legislation extend to, and apply?

4.6 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales.

4.7 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England.

5. Policy Context

What is being done and why?

Regarding prescribing of tadalafil and vardenafil

5.1 On 1 July 1999, formal measures were introduced to restrict NHS prescribing of erectile dysfunction treatments in NHS general practice. The aim of these measures was to limit NHS spending in primary care on the treatment of erectile dysfunction to between £10 and £12 million a year. Adjusting for inflation, this is the equivalent of £18-22 million today.

5.2 Erectile dysfunction treatments were relatively new at that time. The medicines in question were only available by brand and therefore considered expensive.

5.3 In 1999, the treatments affected by the new regulations were alprostadil (Caverject, MUSE and Viridal), moxisylyte hydrochloride/thymoxamine hydrochloride (Erecnos), sildenafil (Viagra) and Cialis (tadalafil). Levitra (vardenafil) was licensed for use in the UK and added to the SLS in 2003.

5.4 Since that time, treatments have been removed from the SLS list as medicines have lost patent protection and cheaper generic versions have provided an affordable alternative, for example sildenafil (the key component of Viagra). The cost of branded Viagra did not change and therefore this treatment remains on the SLS to-date.

5.5 Given the availability of generic tadalafil and generic vardenafil and associated lower prices of each (compared to the branded forms), it is appropriate to remove these two treatments from the SLS and expand the current treatment options that are available to patients in NHS primary care.

Regarding prescribing of oseltamivir (Tamiflu) and zanamivir (Relenza)

5.6 Antivirals – oseltamivir (Tamiflu®) and zanamivir (Relenza®) – are recommended for treatment of those at highest risk of severe disease following a confirmatory test for flu, or within flu season for those with influenza-like infection symptoms. They are also recommended for prophylaxis in specific settings such as care homes where

confirmed cases of flu have occurred. Outside of flu season, prescribing is restricted due to inclusion of both antivirals on the SLS. This can lead to delays in dispensing the medicines. Although the numbers of outbreaks of flu outside of the flu season are low, compared to within the flu season, potential outcomes for people at risk are no less severe.

5.7 Despite previous attempts to improve the efficiency of access to restricted antivirals out of season, including issuing guidance and communications, local commissioning arrangements mean there is variation in the service to provide the antiviral treatments (i.e. locations of commissioned pharmacies). This can create significant delays and affect access to antivirals, which in turn can lead to health consequences for vulnerable people.

5.8 The instrument will remove SLS restrictions on these flu antivirals achieving efficient dispensing of antiviral treatments outside of the flu season, and, potentially, in a pre-pandemic phase of a new or emerging strain of influenza. This will enable oseltamivir and zanamivir to be prescribed and dispensed via standard prescription processes outside of the flu season, improving the efficiency of the process to prescribe the antivirals out of season and reducing delays in access.

5.9 Overall costs will not increase, but there will be a shift in the cost from the locally commissioned service to the community pharmacy contractual framework (CPCF).

5.10 Based on previous prescribing data in England from between 2019 and 2023: the shift in cost, to provide antivirals, from the locally commissioned service to the national community pharmacy contract is estimated to be £13,415.47 per month. Cost per annum £160,985.64 (NB: this volume will include some antivirals that have been prescribed for prophylaxis).

What was the previous policy, how is this different?

Regarding prescribing of tadalafil and vardenafil

5.11 Previously, generic sildenafil was the only medication that could be prescribed in primary care, restriction-free, for the treatment of erectile dysfunction. It was considered the first-choice treatment for erectile dysfunction in local formularies. This appropriately aligned with the expectation that prescribers should choose the most clinically and cost-effective option when making prescribing decisions.

5.12 In cases where generic sildenafil was not effective or tolerated, patients could only access tadalafil and vardenafil in primary care if they met the specific criteria outlined in the SLS. Patients suffering from severe distress on account of their erectile dysfunction could be referred to secondary care for treatment. Patients for whom sildenafil was not tolerated or effective, didn't meet with SLS criteria and weren't experiencing severe distress could therefore only obtain the restricted medicines via private prescription – either via their GP or another legal route.

5.13 This instrument increases the number of treatment options for erectile dysfunction that are available to patients without restrictions within primary care. It means more patients can seek treatment directly from their NHS GP and may reduce the need for some patients to be referred to secondary care.

Regarding prescribing of oseltamivir (Tamiflu) and zanamivir (Relenza)

5.14 Outside of the flu season, which is defined by a notification from the Chief Medical and Pharmaceutical Officers and based on UKHSA advice on epidemic thresholds,

prescribing of oseltamivir (Tamiflu®) and zanamivir (Relenza®) was previously restricted due to their inclusion on the Selected List Scheme (SLS).

5.15 The amendments contained in this instrument enable year-round prescribing of oseltamivir and zanamivir where other conditions are met. This will achieve efficient dispensing of antiviral treatments outside of the flu season and in a potentially pre-pandemic phase of a new or emerging strain of influenza.

5.16 These changes incorporate lessons learnt from the COVID-19 pandemic and reflect improvements in respiratory infection testing, meaning the original rationales for the restrictions no longer apply.

6. Legislative and Legal Context

How has the law changed?

6.1 These regulations amend Schedule 2 to the NHS (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004, which sets out medicines and other substances that can only be ordered on the NHS in certain circumstances.

Why was this approach taken to change the law?

6.2 This is the only possible approach to make the necessary changes as the SLS is set out in regulations.

7. Consultation

Summary of consultation outcome and methodology

Regarding prescribing of tadalafil and vardenafil

7.1 A targeted consultation with The British Medical Association (BMA) and Community Pharmacy England (CPE) sought views on potential benefits to patients and potential extra pressure on General Practitioners (GPs).

7.2 CPE strongly agreed with the department's proposal and expressed a preference for amending the SLS for flu antivirals alongside the erectile dysfunction medications change. CPE requested advance notice and guidance for suppliers and pharmacies to adjust their systems and stated that increased dispensing from government prescribing changes should be reflected in community pharmacy funding.

7.3 The BMA adopted a neutral position, citing concerns about increased workload in general practice from patients switching from private to NHS prescriptions or requiring consultations to change medications. They also requested an impact assessment for general practice. A de minimis impact assessment has been completed, which is considered to adequately address the concerns raised.

7.4 In parallel to the targeted consultation, the proposal was tested with Medicines Optimisation teams from a range of Integrated Care Boards (ICBs), as well as Regional Chief Pharmacists (RCPs). Their views were sought specifically on the benefits of the proposal to patients, impact on GPs and other risks and benefits not otherwise captured. The feedback from this informal engagement was positive and supportive.

Regarding prescribing of oseltamivir (Tamiflu) and zanamivir (Relenza)

7.5 Removing the flu season SLS restrictions on oseltamivir (Tamiflu®) and zanamivir (Relenza®), has been agreed by the Chief Medical Officer and the change has been developed with partners in NHSE, UKHSA and discussed with health stakeholders.

8. Applicable Guidance

8.1 Departmental guidance is not required for changes to the SLS.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

A full Impact Assessment has not been prepared for this instrument because of the projected low impact of the policy on businesses and spending. De Minimis Assessments have instead been prepared for each of the two distinct elements of the SI. The De Minimis Assessment for erectile dysfunction medications will be published alongside the Explanatory Memorandum on Legislation.gov.uk.

Impact on businesses, charities and voluntary bodies

Regarding prescribing of tadalafil and vardenafil

9.1 The impact on pharmacies, some of whom are small businesses, will be minimal as this is a minor change to dispensing arrangements for these medicines. There may be a small increase in prescription volumes while overall revenue is expected to be broadly neutral. Both prescribers and dispensers will benefit from the simpler prescribing process once SLS requirements are removed. There is no direct impact on the third sector.

Regarding prescribing of oseltamivir (Tamiflu) and zanamivir (Relenza)

9.2 There is no, or no significant, impact on business, charities or voluntary bodies charities or voluntary bodies because clinical reasons to prescribe flu antivirals will not change. Prescribing levels are expected to remain broadly consistent with current levels, but patients will receive treatment much faster.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

Regarding prescribing of tadalafil and vardenafil

10.1 We will work with NHS England to monitor any changes in prescribing behaviour resulting from the reform.

Regarding prescribing of oseltamivir (Tamiflu) and zanamivir (Relenza)

10.2 The approach to monitoring this legislation is to monitor prescribing of oseltamivir (Tamiflu®) and zanamivir (Relenza®) via English Surveillance Programme for Antimicrobial Utilisation and Resistance (ESPAUR) and ePACT reports. An evaluation of the change to the legislation will be conducted, including data from frontline regional health protection teams.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 The instrument is being laid on 1st September 2025, allowing more than 21 days before it comes into force on 1st October, which is the next Common Commencement Date. Due to the common commencement date being a set date, some of the parliamentary scrutiny period falls during the recess period on this occasion.

12. European Convention on Human Rights

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

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").