EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL AND LOCAL PHARMACEUTICAL SERVICES) (AMENDMENT) REGULATIONS 2024

2024 No. 838

1. Introduction

1.1 This explanatory memorandum has been prepared by The Department of Health and Social Care and is laid before Parliament by Command of His Majesty.

1.2 This memorandum contains information on amendments to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (SI 2013/349, as amended) ("the PLPS Regulations"). These amendments are to enable the Secretary of State or NHS England to determine that zero or only nominal NHS reimbursement is to be paid to community pharmacies for vaccinations for respiratory syncytial virus (RSV) and measles, mumps and rubella (MMR), if they are supplied or administered to NHS patients as part of NHS pharmaceutical services and they have been centrally purchased and provided to the pharmacies free of charge.

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

2. Declaration

2.1 Minister Stephen Kinnock at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

2.2 Gila Sacks, Director for Medicines, at the Medicines Directorate confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Saira Khan at the Department of Health and Social Care, email: saira.khan@dhsc.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 The amendments provide that, where the Government has centrally purchased RSV and MMR vaccines that are made available to community pharmacies at no cost for supply or administration to NHS patients, the Secretary of State or in some instances NHS England may determine that the amount to be paid by way of NHS reimbursement for product costs to community pharmacies for supplying or administering those vaccines may be set at zero or a nominal amount, if certain conditions are met. This only affects the reimbursement for the product costs. It does not affect the amount that the community pharmacy will be paid for the service cost of supplying or administering the vaccine as part of NHS pharmaceutical services.

Where does the legislation extend to, and apply?

4.2 The territorial extent of this instrument is to England and Wales.

4.3 The territorial application of this instrument is England.

5. Policy Context

What is being done and why?

5.1 Zero or nominal reimbursement of RSV and MMR Vaccines

5.2 The policy context is a desire to enable community pharmacies to use centrally procured RSV and MMR vaccines in specially commissioned services (known as enhanced services) to support NHS England's immunisation programmes.

5.3 The Joint Committee on Vaccination and Immunisation (JCVI) has advised that "there is a significant burden of RSV illness in the UK population and unmet public health need, which has a considerable impact on NHS services during the winter months" and that "an RSV immunisation programme, that is cost effective, should be developed for both infants and older adults".

5.4 NHS England has proposed to commission community pharmacies to provide additional capacity and increased access to supplement the core provision of RSV vaccines. In areas where local need has been identified, local NHS commissioners will be able to competitively procure from community pharmacies an adult RSV vaccination service. The expectation is that, initially at least, there will be a RSV vaccination service for patients aged 75 years, who will remain eligible until they attain 80 years of age, and a RSV in-pregnancy vaccination service for patients from at least 28 weeks of pregnancy.

5.5 From September 2024, approximately 50 'early adopter' community pharmacies will be commissioned to provide the service. The findings from the early adopters and subject to those findings, the proposal is to expand the supplementary service rapidly in due course. This is likely to include up to circa 1,200 community pharmacies across England dependent on identified local needs.

5.6 An MMR vaccination service pilot is already being provided from around 40 community pharmacies as an NHS locally commissioned enhanced service using centrally procured stock supplied to the pharmacies free of charge. As part of the pilot, pharmacies have not been reimbursed for the vaccine, and the legal basis for this needs to be regularised (the Department has only recently been made aware of the pilot). Due to increasing local outbreaks of measles which could have an impact on health services in the Autumn/Winter, NHS England are looking to extend the pilot to at least a further 8 pharmacies.

What was the previous policy, how is this different?

5.7 The expectation under the ordinary reimbursement arrangements for NHS pharmaceutical services is that pharmacies are reimbursed an amount which is in respect of (but ordinarily slightly more than) the price that a service provider paid when they purchased a prescription item that they go on to supply or administer. However, there are powers in Part 7 of the 2006 Act to enable alternatives to these ordinary remuneration arrangements in some circumstances.

5.8 This instrument does not relate to withdrawal from the European Union.

6. Legislative and Legal Context

How has the law changed?

6.1 The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the PLPS Regulations") govern the arrangements in England, under Part 7 of the National Health Service Act 2006 ("the NHS Act"), for the provision of pharmaceutical and local pharmaceutical services. The core pharmaceutical or local pharmaceutical service is the dispensing of NHS prescriptions. However, in addition to that and other "essential" services, there are services known as "advanced" and "enhanced" services that pharmacies providing the "essential" services can chose to provide (in the case of "advanced" services) or are commissioned to provide (in the case of "enhanced" services). Commissioning of "enhanced" services in an NHS England function that can be delegated to local NHS commissioners.

6.2 As is noted above, the scheme for payment for pharmaceutical and local pharmaceutical services in Part 7 of the NHS Act is predicated on the basis that the determining authorities for pharmaceutical remuneration (that is, the Secretary of State and, for some purposes, NHS England) will ordinarily include, in the payments for those services, an amount which is in respect of (but ordinarily slightly more than) the price paid by service providers when they purchased the prescription items that they supply or administer to NHS patients.

6.3 However, section 164 of the 2006 allows for the creation, by regulations, of some statutory exceptions to this principle. The exceptions are to allow for the use of some centrally purchased medicines in the NHS services provided by community pharmacies – and where the medicines are supplied free of charge to the pharmacies, the remuneration for the pharmacies then does not need to include anything for those medicines when the pharmacies go on to supply or administer those medicines for NHS patients. The powers have previously been exercised to support the supply of coronavirus vaccines and antivirals, and now new statutory exceptions are being created for RSV vaccines and MMR vaccines.

Why was this approach taken to change the law?

6.4 This avoids the risk of the NHS paying twice for the product, as the pharmacy would ordinarily be entitled to reimbursement for supplying or administering it, despite receiving it without charge. The changes in this instrument are not intended to radically change NHS pharmaceutical service provisions or payment mechanisms. The aim is to strengthen the legal basis for scenarios when the usual supply routes need to be bypassed to address a public health need. In the circumstances, this is the only possible approach to make the necessary changes.

7. Consultation

7.1 ***Summary of consultation outcome and methodology***

The Department has consulted with the Community Pharmacy England (CPE) on changes to the PLPS Regulations with regards to RSV and MMR vaccination supply with zero reimbursement and they have accepted the amendment. Separately, NHS England has consulted on the RSV vaccination service proposal with CPE.

8. Applicable Guidance

8.1 There will not be any guidance issued by the Department in connection with this instrument. Communication of this sort of change to community pharmacies is ordinarily done by CPE.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because the changes are enabling and facilitative. The vaccines will have been provided free of charge to pharmacies that have chosen to provide the NHSE service.

Impact on businesses, charities and voluntary bodies

9.2 There is no, or no significant, impact on business, charities or voluntary bodies. No adverse impacts are foreseen in the context of the discharge of the Secretary of State's Public Sector Equality Duty or his general duties under the 2006 Act.

9.3 As the PLPS Regulations concern the provision of NHS services in England on the basis of nationally determined terms of service, it is not possible to differentiate between contractors according to their operational turnover or size.

9.4 There is no, or no significant, impact on the public sector.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The Department monitors the implementation and efficient operation of the PLPS Regulations, has consultations with interested parties including the NHS and CPE.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 While this instrument is being laid before Parliamentary more than 21 days before coming into effect, much of the scrutiny period is during recess. It is important that this instrument is progressed now to avoid NHS England having to delay implementation of the RSV vaccination service and further roll out of the MMR vaccination service in community pharmacy, and to increase patient access to vaccines where there are local outbreaks.

12. European Convention on Human Rights

12.1 As the instrument is subject to negative resolution 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").