EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (AMENDMENTS RELATING TO SERIOUS SHORTAGE PROTOCOLS) REGULATIONS 2019

2019 No. 990

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 Her Majesty.

2. Purpose of the instrument

2.1 This instrument amends the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the PLPS Regulations") and the National Health Service (Charges for Drugs and Appliances) Regulations 2015 ("the Charges Regulations") in order to extend the scope of and operationalise Serious Shortage Protocols (SSPs). Where there is a serious shortage of a health care product ordered on an NHS prescription, SSPs issued by the Secretary of State will allow providers of NHS pharmaceutical and local pharmaceutical services to supply a different product or quantity of product in accordance with the SSP, rather fulfilling the original prescription. The standard prescription charge exemptions will apply when a supply is made in accordance with an SSP, except for a case where a reduced quantity of product is supplied, in which case no prescription charge will be payable by any patient.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England.

4.2 The territorial application of this instrument is England.

5. European Convention on Human Rights

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

6. Legislative Context

6.1 The Human Medicines (Amendment) Regulations 2019, which entered into force on 9th February 2019, amended the Human Medicines Regulations 2012 to enable

Ministers to issue SSPs for prescription only medicines (POMs). Before the amendment, which introduced regulation 226A into those Regulations, if a pharmacy could not dispense what was on the prescription for a POM, it needed either to refer the patient back to the prescriber or, if there was an urgent need, to contact the prescriber to discuss an alternative and then get the prescription changed by the prescriber. SSPs allow pharmacists instead to supply in accordance with the SSP, which may allow for the supply of an alternative quantity, an alternative pharmaceutical form, an alternative strength, a therapeutic equivalent or a generic equivalent as indicated in the protocol –without going back to the prescriber.

6.2 These Regulations also extend the scope of SSPs for the purposes of NHS supply on prescription to all drugs and appliances that may be dispensed as part of the provision of pharmaceutical and local pharmaceutical services in England – not just POMs.

6.3 The legislative framework for the provision of pharmaceutical and local pharmaceutical services in England is set by the PLPS Regulations. They provide for pharmaceutical and local pharmaceutical services – which include dispensing services – to be provided by three types of business: community pharmacies (that dispense both drugs and appliances); dispensing doctors (that also dispense both drugs and appliances); and dispensing appliance contractors (DACs - that only dispense appliances). The terms of service of all these types of provider, collectively known as "contractors", are amended by these Regulations. Most of the prescriptions that contractors dispense are issued by GP practices.

7. Policy background

What is being done and why?

7.1 Normally if a contractor is unable to dispense what is on an NHS prescription, they will either send the patient back to the prescriber or, if there is an urgent need, contact the prescriber, discuss an alternative and then get the prescription changed by the prescriber (if the contractor is a dispensing doctor, this will be an internal matter).

7.2 The Department has well established procedures for managing shortages in collaboration with manufacturers and suppliers, clinicians, the NHS and the Medicines and Healthcare Products Regulatory Agency – and SSPs will be an additional tool for use in those processes.

7.3 In a range of circumstances, it may be impractical – or increase the risk to patients – for all patients affected by a serious shortage to return to the prescriber (usually a GP), or for the contractor to liaise with the prescriber about the prescription. An example of where a delay caused by the need for a new prescription could increase the risk to patients is a delay in supplying an auto-injector containing adrenaline needed by a patient in case he or she experiences an allergic reaction. In addition, effective management of shortages of products may prevent products in short supply from running out completely, and so potentially significantly increasing the risks to those patients who are then left with none of the product.

7.4 Avoiding referrals back to a prescriber, where this can be done safely and appropriately, will also enable GPs and other prescribers to focus more time on other patients who are not necessarily affected by the shortage but who need care – including urgent care – for other reasons.

7.5 A protocol would only be introduced in the case of a serious shortage, if it would help manage the supply situation and if clinicians think it is appropriate – and after discussion with the manufacturer and/or marketing authorisation holder. The power to issue protocols is a reserve power that would only be used in exceptional circumstances.

7.6 Ministers in signing off a protocol would be advised by the Medicines Shortage Response Group which is chaired by the Deputy Chief Pharmaceutical Officer for England. They will need to consult clinicians with expertise in the relevant area to provide the clinical content for any protocol. Each protocol would clearly set out what action can be taken by (in most cases) the community pharmacist, under what circumstances, for which patients and during which period.

7.7 The changes to the Human Medicines Regulations 2012 only related to issuing SSPs in relation to POMs. However, as part of NHS pharmaceutical services, community pharmacies, dispensing doctors and DACs dispense a very broad range of products including pharmacy medicines, medicines on general sale, other products treated as "drugs" on NHS prescriptions (such as medical foods) and appliances.

7.8 The extension of SSPs to health care products that are not POMs will have essentially the same benefits to patients as those arising from the most effective management of serious shortages relating to POMs, although these other products are products that community pharmacies can generally supply privately as part of their normal course of business. Nevertheless, in cases where these others products are supplied on the NHS and patients are supported by multiple dosage systems (MDS) – for example trays that have all the medicines that a patient needs to take at a particular time on a particular day in one indent – reducing the circumstances in which a patient needs to be referred back to the prescriber means that the MDS is less likely to include an incomplete set of the medicines that the patient needs to take. This may particularly help patients with memory difficulties.

7.9 If a product supplied by a community pharmacy in accordance with an SSP is a POM that is different to but has the same therapeutic effect as the product originally ordered, the pharmacy must notify the patient's NHS GP practice of the substitution (if the patient has one). A community pharmacy or DAC must also notify a patient's NHS GP practice in other cases of supply in accordance with a SSP, if a requirement to notify that substitution has been agreed with the relevant representative body. This is to ensure appropriate level of communication between healthcare providers which in turn will promote patient safety.

7.10 Also, with patient safety in mind, any product supplied under an SSP by a community pharmacy or a dispensing doctor must bear the 'warning' on the dispensing label to the effect that the product was supplied against an SSP rather than the patients usual prescription (DACs will supply this warning in a separate note). This is to alert patients to the fact that the supply differs from their usual prescription. The precise form of the wording is not set out in the legislation to support flexibility in particular situations.

7.11 If a community pharmacy, DAC or a dispensing doctor makes a supply in accordance with an SSP, the original NHS prescription can no longer be fulfilled. The intention is that the original NHS prescription will be repurposed as the record of the supply in accordance with the SSP for payment and prescription charges purposes. However,

there is a transitional provision to allow for another token to be used, until payment and charging systems are adapted.

7.12 In instances where a community pharmacy or a DAC consider that it is not appropriate for their patient to receive a product in accordance with the SSP and at the same time they cannot dispense what is on the original prescription, they will be obliged to provide the patient or the patient's representative with appropriate advice, as necessary, about reverting to the prescriber for the prescriber to review the patient's treatment.

7.13 If, as a consequence of supplying in accordance with an SSP instead of the original prescription, a patient who would otherwise pay a prescription charge is supplied with a smaller quantity of a drug or fewer appliances, no prescription charge will be payable. For all other supplies made under an SSP, prescription charges and exemption status will apply as usual. This extra exemption is to protect NHS patients who might otherwise lose out financially as a consequence of the SSP.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument does not relate to withdrawal from the European Union. However, if withdrawal from the European Union was a contributing factor to a serious shortage of a product normally available on NHS prescription, a SSP could be issued in those circumstances.

9. Consolidation

9.1 There are no plans currently to consolidate either the PLPS Regulations or the Charges Regulations.

10. Consultation outcome

10.1 The Department of Health and Social Care's normal practice is to consult contractor representative bodies when it changes the PLPS Regulations, rather than consulting more widely or not at all – and it kept to its normal practice in this instance by engaging with the representative bodies that it normally engages with on these occasions – the Dispensing Doctors Association, the British Medical Association, the British Healthcare Trades Association (the representative body of DACs) and the Pharmaceutical Services Negotiating Committee (PSNC – the representative body of retail pharmacy businesses providing NHS services). Consultation responses were broadly supportive of this statutory instrument. Concerns were raised by the PSNC in relation to the workload around SSPs, and these discussions will continue as part of the negotiations on the Community Pharmacy Contractual Framework for 2019/20 and beyond.

11. Guidance

11.1 Operational guidance is under preparation and the intention is that it will be made available on the NHS Business Services Authority's (NHS BSA) website either before the first SSP is issued or alongside the first SSP, which will also be available on the NHS BSA's website.

12. Impact

12.1 The impact on business, charities or voluntary bodies is on retail pharmacy businesses and DACs. The supply in accordance with an SSP instead of in accordance with a prescription will be a more burdensome process for retail pharmacy businesses and DACs, even though some time should be saved in respect of trying to source products that are in short supply. This issue is being considered separately by the Department as part of the consideration of payment arrangements for supply in accordance with a SSP, which is part of the negotiations on the Community Pharmacy Contractual Framework for 2019/20 and beyond mentioned in paragraph 10.1.

12.2 The impact on the public sector is on NHS bodies not normally considered to be businesses, charities or voluntary bodies and is focused mainly on prescribers. SSPs will save GPs' and other prescribers' time because they will save them in many instances from having to issue a replacement prescription. As indicated above, avoiding referrals back to prescribers will mean they are able to focus more on patients who would not be able to have their medicines supplied in accordance with an SSP (i.e. more complex patients) or on other patients who are not necessarily affected by the shortage but who need care – including urgent care – for other reasons.

12.3 An Impact Assessment has not been prepared for this policy. The amendments made by these Regulations are enabling and the new arrangements will only be used when there is a recognised serious shortage. It is not possible to predict the number of serious shortages that might arise, the length of any serious shortages, the nature of the products that might be affected or whether in the particular circumstances of a serious shortage an SSP will be needed as one of the tools used to manage it. Necessarily these issues are very fact dependent, but the expectation is that SSPs will only ever be needed in exceptional circumstances.

12.4 The main benefit of an SSP would be maintaining timely access to treatment for patients. Serious shortages of treatments in themselves present risks to patients, and SSPs will form part of the arrangements for managing those risks. Whilst SSPs have the potential to create new risks, clinician involvement in developing SSPs will minimise those risks. SSPs will never be issued unless they are clinically justified.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise regulatory burdens on small businesses.

13.3 Many community pharmacies are small businesses. Whilst costs savings from GPs are expected, there might be some impact on pharmacy contractors as potentially SSPs will cause an additional workload. However, as indicated above, at the same time savings should be made because pharmacies will not be trying to source products affected by a serious shortage to the same extent.

14. Monitoring & review

14.1 The PLPS Regulations and the Charges Regulations are subject to a regular review by the Secretary of State. The amended provisions will be subject to that review. There will also be a separate review of the provision for SSPs by virtue of regulation 226A(6) of the Human Medicines Regulations 2012 as soon as is reasonably practical after the end of one year after the first such protocol for a POM starts to have effect. This will look at, specifically, any adverse consequences for either the market in

POMs or patient safety. A stakeholder consultation will be conducted as part of the review.

15. Contact

15.1 Michael O'Kane at the Department of Health and Social Care Telephone: 020 7972 4803 or email: Michael.O'Kane@dhsc.gov.uk can be contacted with any queries regarding the instrument.

15.2 Jeannette Howe, Deputy Director for Pharmacy, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 The Secretary of State, the Rt Hon Matt Hancock MP at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.