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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 (S.I. 2013/898 (W. 102)) (“the Pharmaceutical Services Regulations”). The Pharmaceutical Services Regulations govern the arrangements for the provision of pharmaceutical and local pharmaceutical services in Wales, under Part 7 of the National Health Service (Wales) Act 2006 (c. 42).

As a result of amendments made to the Human Medicines Regulations 2012 (S.I. 2012/1916) (“the 2012 Regulations”) by the Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), Serious Shortage Protocols (“SSPs”) may be issued by the Secretary of State and/or the Minister for Health, Social Services and Public Safety in Northern Ireland (either of them acting alone or both of them acting jointly), in circumstances where the United Kingdom or any part of the United Kingdom is experiencing or may experience a serious shortage of a prescription only medicine. SSPs issued under the 2012 Regulations allow pharmacists at retail pharmacy businesses to supply a different prescription only medicine, or a different strength, form or quantity of the prescription only medicine, to that ordered by the prescriber, in the circumstances and subject to the conditions specified within the SSP, without breaching the restrictions on the sale or supply of prescription only medicines in Part 12 of the 2012 Regulations.

These Regulations make a number of consequential changes to the NHS terms of service for NHS pharmacists and NHS appliance contractors in Schedules 4 and 5 to the Pharmaceutical Services Regulations, and make provision in relation to SSPs.

Regulation 2 of these Regulations amends the Pharmaceutical Services Regulations to extend the scope of SSPs. The amendments enable the Welsh Ministers to issue SSPs relating to health care products (drugs and appliances) that are not prescription only. Where the Welsh Ministers are of the opinion that Wales (or a part of Wales) is experiencing, or may experience, a serious shortage of the healthcare product concerned, they may issue a SSP to enable NHS pharmacists and NHS appliance contractors providing pharmaceutical or local pharmaceutical services in Wales, to supply a different product or quantity of product to that ordered on a prescription form. The supply must be in accordance with any conditions contained with the applicable SSP, and only in the circumstances specified.

Where a SSP is in place, the NHS pharmacist or NHS appliance contractor must consider whether it is reasonable and appropriate to supply in accordance with the SSP rather than fulfilling the NHS prescription for that product. Where an NHS pharmacist or NHS appliance contractor does supply in accordance with the SSP, the original NHS prescription must be endorsed accordingly. The original NHS prescription can no longer be fulfilled, and the original prescription form, in its endorsed form, is repurposed as the record of the SSP supply for payment purposes. An NHS pharmacist must include information to the effect that the product is being supplied in accordance with a SSP in the dispensing label on the packaging of the product supplied. An NHS appliance contractor must provide information to the effect that the product is being supplied in accordance with a SSP, in a written note for the patient’s benefit (regulations 3(2), (3) and (4)(e) and 4(2), (3) and (4)(c)).

If a product supplied by (or under the supervision of) an NHS pharmacist in accordance with a SSP is a prescription only medicine that is different to but has a similar therapeutic effect to the product originally ordered, the NHS pharmacist must notify the patient’s NHS GP practice of the substitution (if the patient has one). An NHS pharmacist or NHS appliance contractor must also notify a patient’s NHS GP practice in other cases of a supply in accordance with a SSP, if a requirement to notify has

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

been agreed between the Welsh Ministers and the relevant representative body for consultation in relation to pharmaceutical remuneration (regulations 3(2) and 4(2)).

If an NHS pharmacist or NHS appliance contractor does not think it reasonable or appropriate to supply in accordance with a SSP, but is unable to fulfil the original prescription with reasonable promptness (the normal timescale required for fulfilling prescriptions), they will not breach the NHS terms of service if the original prescription is nevertheless fulfilled within a reasonable timescale (regulations 3(2) and 4(2)).

Where an NHS pharmacist or NHS appliance contractor does not think it reasonable or appropriate to supply in accordance with a SSP but cannot fulfil the original prescription within a reasonable timescale, they may refuse to dispense the product in question. If they do refuse to do so, they must 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 (regulations 3(5) and 4(5)).

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has been prepared as to the likely costs and benefits of complying with these Regulations. A copy can be obtained from Welsh Government, Cathays Park, Cardiff, CF10 3NQ and is published on [www.gov.wales](http://www.gov.wales) .