

Health, Social Care and Sport Committee

SSI cover note

11th Meeting, (Session 6), 16 November 2021

This paper invites the Committee to consider the following negative instruments:

- National Health Service (Pharmaceutical Services) (Scotland) Amendment Regulations 2021 (SSI 2021/367)

Parliamentary procedure:

Negative instruments are instruments that are “subject to annulment” by resolution of the Parliament for a period of 40 days after they are laid. This means they become law unless they are annulled by the Parliament. All negative instruments are considered by the Delegated Powers and Law Reform Committee (on various technical grounds) and by the relevant lead committee (on policy grounds).

Under Rule 10.4, any member (whether or not a member of the lead committee) may, within the 40-day period, lodge a motion for consideration by the lead committee recommending annulment of the instrument.

If the motion is agreed to by the lead committee, the Parliamentary Bureau must then lodge a motion to annul the instrument to be considered by the Parliament as a whole. If that motion is also agreed to, the Scottish Ministers must revoke the instrument.

If the Parliament resolves to annul an SSI then what has been done under authority of the instrument remains valid but it can have no further legal effect. Following a resolution to annul an SSI the Scottish Ministers (or other responsible authority) must revoke the SSI (make another SSI which removes the original SSI from the statute book.) Ministers are not prevented from making another instrument in the same terms and seeking to persuade the Parliament that the second instrument should not be annulled.

For decision

The Committee is invited to consider any issues it wishes to raise regarding this instrument.

Title of Instrument: [National Health Service \(Pharmaceutical Services\) \(Scotland\) Amendment Regulations 2021\(SSI 2021/367\)](#)

Laid Date: 28 October 2021

Reporting deadline: 29 November 2021

Type of instrument: Negative

Background

Regulation 248 of The Human Medicines Regulations 2012 provides an exception to the normal rules regarding supply of medicinal products, allowing for the collection of prescriptions for, and delivery of such products from premises which are not a registered pharmacy in certain circumstances. The existing National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009, prevent pharmaceutical services being provided other than at a registered pharmacy.

Purpose

This instrument amends the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 to allow for the provision of dispensed medicines at premises which are not a registered pharmacy. This is in line with the exception created by regulation 248 of the Human Medicines Regulations 2012.

A copy of the Scottish Government's Policy Note is included in **Annexe A**.

Delegated Powers and Law Reform Committee consideration

The Delegated Powers and Law Reform Committee considered the instrument at its meeting on 9 November 2021 and made no recommendations in relation to this instrument.

ANNEXE A

**POLICY NOTE
THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES)
(SCOTLAND) AMENDMENT REGULATIONS 2021
SSI 2021/367**

The above instrument was made in exercise of the powers conferred by sections 27, 28(2) and 105(7) of the National Health Service (Scotland) Act 1978. The instrument is subject to negative procedure.

This instrument amends the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 to permit the dispensing of medicinal products from premises which are not a registered pharmacy premises as part of collection and delivery arrangement as defined by regulation 248 of The Human Medicines Regulations 2012.

Policy Objectives

Regulation 248 of The Human Medicines Regulations 2012 provides an exception to the normal rules regarding supply of medicinal products, allowing for the collection of prescriptions for, and delivery of such products from premises which are not a registered pharmacy in certain circumstances. The existing National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009, (“the 2009 regulations”) prevent pharmaceutical services being provided other than at a registered pharmacy. This is contrary to regulation 248 of the Human Medicines Regulations 2012 in respect of the collection and delivery of medicines. The amendments will allow for the provision of dispensed medicines at premises which are not a registered pharmacy, in line with the exception created by regulation 248 of the Human Medicines Regulations 2012.

Consultation

The Scottish Government consulted with the contractors’ representative body in Scotland, Community Pharmacy Scotland, on terms of the amendments to the 2009 regulations and the operational guidance for collection and delivery services.

Impact Assessments

An impact assessment has not been prepared for this instrument. The amendments made by these regulations are enabling and the amended arrangements for collection and delivery of medicines will have minimal impact on the provision of prescription medicines dispensed by community pharmacy contractors. The use of collection and delivery arrangements provide patients with additional options for accessing their prescribed medicines both in and out of hours. The operational model to provide a collection and delivery is a commercial choice by the community pharmacy contractor. Those existing providers in the same area may see a decrease in dispensing activity should some patients choose to access such services from contractors who offer collection and delivery services for prescription medicines.

Financial Effects

No BRIA has been completed as the instrument has no financial effects on the Scottish Government or Health Board finances. Collection and delivery services do not form part of the remuneration arrangements for the provision of pharmaceutical care services.

Scottish Government
Directorate for Chief Medical Officer
Pharmacy and Medicines
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