POLICY NOTE

THE NATIONAL HEALTH SERVICE (SERIOUS SHORTAGE PROTOCOLS) (MISCELLANEOUS AMENDMENTS) (SCOTLAND) REGULATIONS 2019

SSI 2019/284

The above instrument was made in exercise of the powers conferred by section 17E, 17N, 27, 28(1) and 105(7) of the National Health Service (Scotland) Act 1978(a). The instrument is subject to negative procedure.

This instrument amends the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009, The National Health Service (General Medical Services Contract) (Scotland) Regulations 2018 and The National Health Service (Primary Medical Services Sections 17C Agreements) (Scotland) Regulations 2018 in order to extend the scope and operationalise Serious Shortage Protocols (SSPs). Where there is a serious shortage of a prescription only medicine or other drug or appliance ordered on an NHS prescription form, SSPs will allow pharmacists and dispensing doctors to supply a different product or quantity or strength in accordance with the SSP, rather than fulfilling the original prescription.

Policy Objectives

Amendments to The Human Medicines Regulations 2012, which entered into force on 9th February 2019, enabled UK Ministers to issue Serious Shortage Protocols ("SSPs") for prescription on medicines (POMs). This SSI amends The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 to allow community pharmacists to operate under an SSP issued by UK Ministers.

Amendments also made to the English equivalent Regulations, The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, made provision for UK Ministers to issue SSPs in England only for all other drugs / appliances which are not POMs. This SSI allows Scottish Ministers to issue a Scottish SSP for all other drugs and appliances classed as in serious shortage.

Previously, if a community pharmacy could not dispense what was on the prescription, the pharmacists needed either to refer the patient back to the prescriber or, if there was an urgent need, contact the prescriber to discuss an alternative and then get the prescription changed by the prescriber.

This instrument allows pharmacists within a community pharmacy to supply in accordance with a SSP issued under the Human Medicines Regulations 2012, 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.

This instrument also creates another type of SSP where Scotland or any part of Scotland is experiencing or may experience a serious shortage of a drug or appliance, which is not a POM. In these circumstances, the Scottish Ministers can issue a "Scottish Serious Shortage Protocol" ("Scottish SSP") – community pharmacists will be able to supply a different drug/appliance or

quantity or strength of the drug/appliance without the need to go back to the prescriber. Dispensing doctors will also be able to supply a different drug or appliance or quantity or strength of the drug or appliance where a Scottish SSP is in place.

The Scottish Government and NHS Scotland have well established procedures for managing medicines shortages, and Scottish Government work collaboratively with UK Government and the Medicines and Healthcare Products Regulatory Agency in order to manage supply issues when they occur, SSPs will provide an additional tool for the purposes of managing shortages. It will be impractical for patients and a burden on NHS Primary Care services for all patients affected by a serious shortage to return to the prescriber, usually a GP, or for the pharmacist to liaise with the prescriber for each individual prescription. As an example, a delay caused by the need for a new prescription could increase the risk to patients requiring a supply of an auto-injector which would be needed should the patient experience an allergic reaction. In addition, the effective management of shortages of products may prevent products in short supply from running out completely, and so potentially significantly decreasing the risk to those patients who would otherwise be left with none of the product.

Avoiding referrals back to a prescriber, where an alternative supply can be made safely and appropriately, will also enable GPs and other prescribers to focus more time on other patients care needs, including urgent care.

The power to issue a SSP (POM only) is reserved to UK Government and would only be used in exceptional circumstances.

"Scottish SSPs" for all other drugs and appliances than POMs may be issued by Scottish Minsters. Ministers signing off a "Scottish SSP" will be advised by the Medicines Shortage Response Group Scotland (MRSG(Sco)) which is chaired by the Chief Pharmaceutical Officer for Scotland. The MRSG(Sco) will consult with expertise in the relevant area to provide the clinical content for any protocol for a "Scottish SSP". Each protocol will clearly set out what action can be taken by the pharmacist, under what circumstances, for which patients and during which period.

The instrument does not relate to the UK's 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 an NHS prescription form, a SSP may be issued by UK Ministers. For all other drugs/appliances that are not POMs, Scottish Ministers may issue a Scottish SSP should they consider a serious shortage is in place in those circumstances.

Consultation
The Scottish Government consulted with the contractors' representative body in Scotland, Community Pharmacy Scotland, on both terms of the amendments to the 2009 Regulations and the operational guidance for pharmacists in the event of an SSP. NHS Boards were also consulted.

Impact Assessments
Impact assessments have not been prepared for this instrument as there is no change in accessibility to the pharmaceutical services being delivered by community pharmacies for patients. 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 duration and the nature of the products that

may be affected. This will be driven by intelligence gathering at the time, but expectation is that SSPs will only ever be needed in exceptional circumstances.

SSPs would ensure the timely access to treatments for patients. Serious shortages of treatments in themselves present risks to patients.

Financial Effects

No BRIA is considered to be required. The financial impact of medicine shortages are part of the day to day operations of the NHS in Scotland. In the event of a medicine shortage, drug costs are likely to increase as a result of more demand for less available products. SSPs will not eliminating the potential for increased costs but will endeavour to mitigate by providing alternative available product for dispensing to patients. SSPs will help in reducing the costs to the NHS in Scotland in both time and resource for new prescription forms being completed by prescribers as a result of a serious shortage.

Scottish Government
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11 September 2019