POLICY NOTE

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES) (SCOTLAND) AMENDMENT REGULATIONS 2020

SSI 2020/420

The above instrument was made in exercise of the powers conferred on Scottish Ministers by sections 27, 28A, 105(7) and 106(a) 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 ("the 2009 Regulations") in respect of allowing pharmacists to provide pharmaceutical services in certain circumstances while a disease is or in anticipation of a disease being imminently pandemic, as well as changes to the Chronic Medication Service which will be re-named the "Medicines: Care and Review Service".

Policy Objectives

This instrument amends the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 ("the 2009 Regulations") following amendments to the Human Medicines Regulations 2012 and the Misuse of Drugs Regulations 2001 to allow community pharmacists in Scotland to provide pharmaceutical services in certain circumstances where a disease is or in anticipation of a disease being imminently pandemic. This instrument also amends the 2009 Regulations to allow pharmacists in Scotland to operate under existing provisions in the Human Medicines Regulations 2012 which relate to the supply of medicinal products in the event or anticipation of pandemic disease.

This instrument amends the 2009 Regulations to allow community pharmacists to supply/administer coronavirus or influenza vaccines in accordance with a protocol under regulation 247A of the Human Medicines Regulations 2012 (inserted by S.I. 2020/1125) as a pharmaceutical service. This is intended to assist with the expansion of the workforce required to administer and support the delivery of vaccination programmes while a disease is, or in anticipation of a disease being imminently pandemic and a serious risk, or potentially a serious risk to human health.

This instrument also amends the 2009 Regulations to allow community pharmacists to supply a prescription only medicine in accordance with a protocol under regulation 247 of the Human Medicines Regulations 2012. A protocol can be put in place where a disease is or in anticipation of a disease being imminently pandemic and a serious risk, or potentially a serious risk to human health to allow pharmacists to supply a prescription only medicine for the treatment of that disease without the need for a prescription.

In addition, this instrument amends the 2009 Regulations to allow pharmacists to provide pharmaceutical services , in response to an announcement of the Secretary of State and arrangements made in accordance with regulation 10A or 15(5) of the Misuse of Drugs Regulations 2001. These provisions in the Misuse of Drugs Regulations 2001 relate to the supply of certain controlled drugs by pharmacists without a prescription and pharmacists changing the intervals of prescriptions for certain controlled drugs where a disease is or in

anticipation of a disease being imminently pandemic and a serious risk or potentially serious risk to human health.

The Scottish Government introduced the Chronic Medication Service (CMS) as an NHS community pharmacy service in 2009. The 2009 Regulations included references to the 'Chronic Medication Service' and introduced provisions for 'serial prescriptions' and 'serial prescribers' to form part of CMS.

Programme for Government 2018 included a commitment to strengthen and refresh CMS. The service will be re-named 'Medicines: Care and Review Service' and this is reflected in this instrument which amends the 2009 Regulations.

This instrument also amends the 2009 Regulations to extend the definition of a 'serial prescriber' to enable nurse independent prescribers (other than supplementary prescribers) and pharmacist independent prescribers who are based within GP practices to write serial prescriptions, in addition to GPs. This is intended to give more flexibility to GP practices and support workload capacity.

The requirement for a person to be registered for CMS before they can receive a serial prescription is removed. This will enable GP practices to identify individuals on their patient list who could benefit from having a serial prescription and then write the serial prescription ahead of the individual registering for the Medicines: Care and Review Service at their local community pharmacy. The person would then register for the service before the community pharmacy dispenses in accordance with a serial prescription. This approach is intended to streamline patient pathways and improve the management of serial prescriptions.

This instrument also makes minor and consequential amendments to the 2009 Regulations, including updating a reference to a regulation in the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2018/66 and in relation to the circumstances in which a pharmacist may refuse to supply drugs or appliances, for example, where the pharmacist is subjected to or threatened with violence or a person presenting a prescription form commits or threatens to commit a criminal offence. This provision is currently limited to where a patient presents a prescription form or serial prescription but this instrument amends the 2009 Regulations to extend the application of this provision to the supply of drugs or appliances under the 2009 Regulations generally, for example, when supply is to take place under a pandemic treatment protocol (PTP).

Impact Assessments

Impact assessments have not been prepared for this instrument as the amendments are to achieve changes to an existing community pharmacy service and the existing process of serial prescriptions and allow the provision of pharmaceutical services in a pandemic disease situation. No impact upon business, charities or voluntary bodies is foreseen.

Financial Effects

The Cabinet Secretary confirms that no BRIA is necessary as the instrument has no financial effects on the Scottish Government, local government or on business.

Scottish Government
Chief Medical Officer Directorate
Pharmacy and Medicines Division
December 2020