

Statutory Instruments with Clear Reports

21 October 2019

SL(5)455 – The National Health Service (Amendments Relating to Serious Shortage Protocols) (Wales) Regulations 2019

Procedure: Negative

The National Health Service (Amendments Relating to Serious Shortage Protocols) (Wales) Regulations 2019 (“these Regulations”) amend the terms of service for NHS pharmacists in Wales to facilitate compliance with Serious Shortage Protocols (“SSPs”) issued under the Human Medicines Regulations 2012.

These Regulations will also extend the definition and scope of a SSP to include a written protocol issued by Welsh Ministers, in circumstances where Wales, or any part of it is, in the opinion of the Welsh Ministers, experiencing or may experience a shortage of a specified drug (other than one which is a prescription only medicine) or appliance or a drug (other than one which is a prescription only medicine) or appliance of a specified description.

The Human Medicines (Amendment) Regulations 2019 (“the amendment Regulations”) came into force on 9 February 2019 and amended the Human Medicines Regulations 2012 to provide for the sale or supply of prescription only medicines by a pharmacist under an SSP issued by the Secretary of State for Health and Social Services and the Ministers of Northern Ireland (medicines regulation being a devolved matter in Northern Ireland) and either of them acting alone or both of them acting jointly.

The amendment Regulations give the Secretary of State and NI Ministers powers to issue SSPs where, in their opinion, the United Kingdom or part of the United Kingdom is experiencing, or may experience, a severe shortage of particular prescription only medicines. The SSPs are designed to allow for



substitution by pharmacists and, only in restricted circumstances, of a different form, quantity, or strength of a prescription only medicine, or a different prescription only medicines, to that ordered by the prescriber.

The Welsh Ministers assert that SSPs will improve the means by which the Welsh Government can manage critical shortages of medicines.

Parent Act: National Health Service (Wales) Act 2006

Date Made: 08 October 2019

Date Laid: 10 October 2019

Coming into force date: 31 October 2019

