
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 (“the 2012 Regulations”).

Regulation 3 updates the general interpretation provisions in the 2012 Regulations to insert new definitions of radiation emergency and paramedic independent prescriber and to add paramedics to the list of health professionals who are included in the definition of a supplementary prescriber.

Regulations 4 to 10 and 13 are required to enable paramedic independent prescribers to mix, prescribe, sell or supply certain type of prescription only medicines.

Regulation 11 amends the 2012 Regulations to ensure that the new provisions are subject to review by the Secretary of State.

Regulation 12 amends Schedule 17 to the 2012 Regulations so that pharmacy medicines containing Potassium Iodide or Potassium Iodate can be supplied in the event of a radiation emergency by persons acting in accordance with an off-site emergency plan or by persons listed in Part 1 or 2 of Schedule 1 to the Civil Contingencies act 2004.

Amendments to the Human Medicines Regulations 2012 are subject to the requirements of the Statutory Rules (NI) Order 1979 and the corresponding SI in respect of this Statutory Rule is S.I. 199/2018.

An assessment of the impact of S.I. 199/2018 on the private and public sector has been prepared in relation to the amendments for paramedic independent prescribers. A copy of that impact assessment is published with the Explanatory Memorandum alongside the instrument on www.legislation.co.uk. Copies may also be obtained from the Department of Health and Social Care, 2E14 Quarry House, Leeds, LS2 7UE. A full impact assessment has not been produced for the amendments relating to Potassium Iodide and Potassium Iodate as no, or no significant, impact on the private, voluntary or public sectors is foreseen. However, an impact statement has been prepared and is available on request from the Department for Business, Energy and Industrial Strategy, 1 Victoria Street, London, SW1H 0ET.