

EXPLANATORY MEMORANDUM TO
THE HUMAN MEDICINES (AMENDMENT) REGULATIONS 2018
2018 No. 199

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health and Social Care (DHSC), and is laid before Parliament by Command of her Majesty
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

- 2.1 These Regulations amend the Human Medicines Regulations 2012 (“the 2012 Regulations”). They do so in order to:
- introduce independent prescribing for registered paramedics and
 - allow the supply of Potassium Iodide and Potassium Iodate (referred to subsequently as “stable iodine”) in the event or anticipation of a radiation emergency.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 Due to an administrative oversight by DHSC, there has been an unintended delay between the making and laying of these Regulations. The Department apologises for this error.

Other matters of interest to the House of Commons

- 3.2 As this instrument is subject to the negative procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

4. Legislative Context

Registered paramedics

- 4.1 Part 12 of the 2012 Regulations sets out who can prescribe, sell, supply and administer as well as receive stocks of medicinal products. Under Part 12 of the 2012 Regulations, medicines which are classed as prescription only medicines (POM) can only be sold or supplied in accordance with an appropriate practitioner’s prescription. An appropriate practitioner includes a doctor, dentist or other independent prescriber. Part 12 also allows supplementary prescribing which is an arrangement whereby, after a diagnosis by an independent prescriber, the supplementary prescriber can prescribe medicines as part of a clinical management plan agreed with the independent prescriber for an individual patient.

Supply of stable iodine

- 4.2 Stable iodine is classed as a pharmacy medicine. Under Part 12 of the 2012 Regulations, medicines which are classed as pharmacy medicines can only be supplied from registered pharmacy premises by, or under the supervision of, a pharmacist. Schedule 17 of the 2012 Regulations sets out certain persons who are exempted from these restrictions in respect of certain medicines.

5. Extent and Territorial Application

- 5.1 This instrument extends to all of the United Kingdom.
5.2 The instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

- 6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

What is being done and why

Registered paramedics

- 7.1 The instrument permits registered paramedics who are appropriately qualified, to independently prescribe medicines (including a limited list of controlled drugs) and to mix medicines. It will also add paramedics to the list of health professionals who can enter into supplementary prescribing arrangements.
- 7.2 Over recent years, changes to the law have permitted a number of professions other than doctors and dentists to play an increasing role in prescribing and managing medicines for their patients. Increasing access to prescribing and medicines supply mechanisms has the potential to improve quality of patient care. It also makes better use of professional skills.
- 7.3 Under current legislation, except in very restricted circumstances, a person mixing drugs together, where one is not a vehicle for the administration of the other, must hold a manufacturer's licence. There is an exemption from this restriction which allows doctors, dentists and other independent prescribers to mix or direct others to mix. As mixing of medicines occurs in paramedic practice, the exemption is being extended to include paramedic independent prescribers.

Supply of stable iodine

- 7.4 The use of stable iodine is a key countermeasure in radiation emergencies. It acts as an effective means of decreasing levels of thyroid cancer in the event of exposure to radioactive iodine, provided it is taken prior to exposure or within a few hours after exposure. Currently, stable iodine is pre-distributed to local populations in limited areas around radiological sites. There is also a national stockpile – however, the restrictions on stable iodine as a pharmacy medicine limit the ability for it to be rapidly distributed to the public in the event of a radiation emergency. This could mean that the effectiveness of stable iodine as a countermeasure is diminished.

- 7.5 This instrument allows persons supplying medicinal products under specific emergency plans in England, Scotland and Wales, as well as persons and bodies listed in the Civil Contingencies Act 2004, to obtain stocks of stable iodine and supply it to the public in the event of a radiation emergency or where such an emergency is anticipated. Widening access to stable iodine in this limited way will retain appropriate safeguards for it as a pharmacy medicine, while giving local authorities and others involved in planning for radiation emergencies greater flexibility for its distribution during the extreme time pressures of a radiation emergency. This will help ensure the effectiveness of stable iodine in radiation emergencies and thereby help safeguard public health.

Consolidation

- 7.6 The majority of medicines legislation was consolidated in 2012 as the Human Medicines Regulations 2012. There are no plans currently to repeat the exercise.

8. Consultation outcome

Registered paramedics

- 8.1 NHS England (NHSE) led the consultations on the proposals for paramedics which took place during February to May 2015. In addition to publication on the NHSE website, the proposals were circulated to the NHS, local authorities and a range of patient and representative bodies. A majority of respondents (over 90%) supported the proposals for paramedics to become independent prescribers.

Supply of stable iodine

- 8.2 The Department for Business, Energy and Industrial Strategy (BEIS), the Ministry of Defence (MOD) and the Health and Safety Executive (HSE) jointly consulted on the proposals for stable iodine which were part of a wider programme of work to make changes to the UK's regulatory framework for radiological emergency preparedness arising from the implementation of the Basic Safety Standards Directive 2013. There were 12 responses which related to the proposals for stable iodine. None of the responses in the consultation went against the government's policy objective of increasing the flexibility of the provision of stable iodine in the event of a radiation emergency. Respondents mostly focused on the need to give Local Authorities more freedom in deciding their own emergency preparedness and response arrangements, which these regulatory changes will help deliver. The Government response to the wider consultation, which will set out this analysis in more detail, will be published in due course.

9. Guidance

- 9.1 The Health and Care Professions Council and the relevant professional representative bodies will issue guidance on the changes relating to paramedics. BEIS will work with other relevant Departments and bodies to develop any supporting guidance as appropriate for the stable iodine changes.

10. Impact

Registered Paramedics

- 10.1 An impact assessment is attached and will be published alongside the Explanatory Memorandum on the legislation.gov.uk website. The proposals for paramedics do not have any significant impact on business, charities or voluntary bodies.
- 10.2 The impact on the public sector is principally to benefit patient care, by providing improved access to the medicines required by patients.

Supply of stable iodine

- 10.3 A full impact assessment has not been prepared for the stable iodine proposal because the legislative measures are small and deregulatory and do not have a direct impact on business. The impact on the public sector is principally to protect public health. An impact statement has been prepared and is available on request (see paragraph 13 below). The threshold criteria for requiring a Regulatory Triage Assessment or full Impact Assessment for the changes were not met.

11. Regulating small business

- 11.1 The legislation does not apply to activities that are undertaken by small businesses.

12. Monitoring & review

- 12.1 The Human Medicines Regulations 2012 is subject to a regular review by the Secretary of State. This instrument makes the amended provisions subject to that review.

13. Contact

- 13.1 Anne Ryan at the MHRA (Telephone: 0208 080 6392 or email: anne.ryan@mhra.gsi.gov.uk) can answer any queries regarding the amendments.