EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENT) REGULATIONS 2015

2015 No. 323

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 is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 These Regulations amend the Human Medicines Regulations 2012. They do so in order to allow supply and administration of medicines under a patient group direction (PGD) by paramedics employed by Maritime and Coastguard Agency contracted helicopter search and rescue operators. The Regulations also allow Public Health England, which is an executive agency of the Department of Health, and its equivalent in Northern Ireland, the Public Health Agency, to supply prescription only medicines under a PGD.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Context

4.1 Under Part 12 of the Human Medicines Regulations 2012, medicinal products which are classed as a prescription only medicine (POM) or a pharmacy medicine (P) can only be sold or supplied at registered pharmacy premises. POMs are subject to the additional requirement that they must be sold or supplied in accordance with an appropriate practitioner's prescription. An appropriate practitioner includes a doctor, dentist or other independent prescriber.

4.2 PGDs provide an exemption from these restrictions. A PGD is a written instruction for the supply or administration of medicines to patients in a defined clinical situation. They can only be used by certain groups of registered health professionals and must be authorised by a relevant appropriate body. Additionally, the use of PGDs is restricted to NHS bodies and other specific settings such as the armed forces.

4.3 A further exemption allows registered paramedics to administer a list of injectable medicines on their own initiative for the immediate necessary treatment of sick or injured persons.

5. Territorial Extent and Application

5.1 This 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

Helicopter search and rescue operators

7.1 Provision for helicopter search and rescue services will move from a service provided by the armed forces and civilian operators under contract to the Maritime and Coastguard Agency (MCA) to a wholly contracted service in 2016. Two companies currently provide a UK-wide service which is collectively referred to as UK SAR. Both employ registered paramedics. While paramedics are one of the groups of health professional who can access PGDs, there is no provision for their use in helicopter search and rescue settings. The lack of access to PGDs means that paramedics employed by the companies cannot use the same range of medicines as their counterparts in the NHS and armed forces.

7.2 In 2012, UK SAR asked the MHRA if the law could be amended to allow the service to use PGDs. Their request was supported by the MCA. These Regulations will allow MCA contracted UK SAR providers to authorise PGDs for use by their registered paramedics so they can offer the same level of care to patients that would be available in the NHS and armed forces.

Public Health England and the Public Health Agency

7.3 Public Health England and the Public Health Agency in Northern Ireland are currently legally unable to authorise PGDs for use in their organisations.

7.4 One of the core functions of Public Health England is to ensure there are effective arrangements in place for preparing, planning and responding to health protection concerns and emergencies. At present,

the NHS generally responds to these situations by providing supplies of medicines but the Department of Health considers there may be exceptional circumstances where Public Health England needs to supply and administer medicines. This is likely to be the case in large scale and high risk situations where a speedy response is required.

7.5 The amending Regulations will enable Public Health England to use PGDs. At the request of the Department of Health, Social Services and Public Safety (Northern Ireland), the equivalent body in Northern Ireland, the Public Health Agency, will also be allowed to use PGDs.

- Consolidation

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

8. Consultation outcome

Helicopter search and rescue operators

8.1 The MHRA consulted interested organisations and published the consultation document on the GOV.UK website. Eleven replies were received. These included responses from medical, pharmaceutical and ambulance organisations. Ten of the responses expressed support for the proposals. The remaining reply could not endorse the proposal unless UK SAR was required to register with the Care Quality Commission although it recognised that there was a need for paramedics in the service to be able to administer drugs and PGDs were an appropriate option.

Public Health England and the Public Health Agency

8.2 The MHRA and Department of Health published a joint consultation document which was also published on the GOV.UK website. There were 16 replies. These included responses from medical organisations, NHS bodies and individuals. All the respondents supported the proposals. The outcome of the consultation, alongside the original consultation document, can be accessed here: https://www.gov.uk/government/consultations/amendments-to-human-medicines-regulations-2012

9. Guidance

9.1 Existing MHRA guidance on PGDs is available and NICE has also published relevant good practice guidelines.

10. Impact

10.1 An Impact Assessment has not been prepared for this instrument. The proposals for UK SAR are minor and have no wider impact on business, charities or voluntary bodies. In relation to Public Health England and the Public Health Agency, there are no significant costs associated with enabling them to use PGDs.

11. Regulating small business

11.1 The legislation does not apply to small business.

12. Monitoring & review

12.1 The Human Medicines Regulations 2012 are subject to a regular review by the Secretary of State.

13. Contact

13.1 Anne Ryan at the MHRA (anne.ryan@mhra.gsi.gov.uk or telephone 0203 080 6392) can answer any queries on the instrument.