EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENT) (No. 3) REGULATIONS 2015

2015 No. 1503

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 Amendment Regulations 2012 ("the 2012 Regulations"). They do so in order to allow drug treatment services provided by or on behalf of NHS bodies and local authorities (LAs) to supply Naloxone Hydrochloride for administration in emergencies involving a heroin overdose. These Regulations also allow Public Health England and the Public Health Agency to enter into arrangements with pharmacies to sell, supply and/or administer medicines under patient group directions (PGDs). Finally, they make minor corrections by updating cross-references and removing redundant provisions in the 2012 Regulations.

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

3.1 None

4. Legislative Context

4.1 Part 12 and Schedule 17 of the 2012 Regulations sets out who can sell, supply and administer as well as receive stocks of medicinal products. Naloxone Hydrochloride is licenced as a prescription only medicine (POM) and under the current provisions is not available for supply in drug treatment services without the services of a doctor or other independent prescriber.

4.2 Under Part 12 of the 2012 Regulations, medicines which are classed as prescription only (POM) or pharmacy (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.

4.3 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 the NHS and other specified bodies – for example, Public Health England and the Public Health Agency.

4.4 NHS bodies, Public Health England and the Public Health Agency can also make arrangements with third parties who are not pharmacies to supply and administer medicines under a PGD. A separate provision allows the NHS and certain other bodies to enter into arrangements with pharmacies to sell, supply and or administer medicines under PGDs but this does not currently extend to Public Health England and the Public Health Agency.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

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

Availability of Naloxone

7.1 The Advisory Council on the Misuse of Drugs (ACMD) is an independent expert body that advises Government on drug-related issues in the UK. In 2012, the ACMD advised that Naloxone should be made more widely available as a way of reducing deaths from heroin overdoses. Currently, drug treatment services are commissioned by the NHS and local authorities. These Regulations will allow those services to obtain stocks of Naloxone Hydrochloride and supply it to anyone requiring access for use in an emergency involving a heroin overdose. This will include drug users, their family members and carers. It will also include other people likely to come into contact with drug users such as hostel managers.

Public Health England and the Public Health Agency

7.2 Public Health England and the Public Health Agency in Northern Ireland are currently legally unable to make arrangements with pharmacies to use PGDs. This was not the policy intention when the 2012 Regulations were amended in April this year to allow these bodies to use PGDs. The Department of Health, Social Services and Public Safety (Northern Ireland) drew the MHRA's attention to the oversight and the Agency agreed to include the provision at the next available opportunity.

7.3 Separately, the MHRA has identified some minor inaccuracies in the 2012 Regulations and is taking the opportunity to correct them.

- Consolidation

7.4 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

Availability of Naloxone

8.1 The MHRA and the UK Health Departments jointly consulted interested organisations. The consultation letter was also published on the MHRA website. A total of 122 responses were received to the consultation. There was near-unanimous support (118 responses) for making the changes to the 2012 Regulations to widen access to Naloxone. The remaining responses did not object but did not answer the question of support clearly. Respondents came from a wide variety of patient-facing services and representative bodies including the Guild of Healthcare Pharmacists, the Royal College of Psychiatrists and the National Offender Management Service. Those in contact with injecting drug users included GPs, nurses, pharmacists, paramedics, drug treatment service and NSP staff and managers in the NHS and voluntary sector, prisons, family members, friends and carers, hostel staff and managers, trainers and researchers. The outcome of the consultation can be accessed here: https://www.gov.uk/government/consultations/proposal-to-allow-wider-access-to-naloxone-for-use-in-emergencies

Public Health England and the Public Health Agency

8.2 The MHRA and Department of Health published a joint consultation document on the original proposals to allow Public Health England and the Public Health Agency to use PGDs. This was also published on the GovUK website. There were 16 replies. These included responses from medical organisations, NHS bodies and individuals. All the respondents supported the proposals.

8.3 No consultation was carried out on the amendments to make minor corrections to the 2012 Regulations.

9. Guidance

Availability of Naloxone

9.1 In February 2015, Public Health England published advice for commissioners and providers of drug treatment services on the provision of naloxone to enable them to take action both in advance and following the amendments to the 2012 Regulations. Public Health England is considering whether it will need to publish any supplementary advice. The need for additional advice will depend on guidance from the working group updating the 2007 UK clinical guidelines on the management of drug misuse and dependence.

Public Health England and the Public Health Agency

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

10. Impact

Availability of Naloxone

10.1 The expected impact on business in the UK which produce and/or sell naloxone products, will be an increase in production and sales, with an estimated net benefit of £8,600 each year and thus a net present value of £99,000 over the ten year period.

10.2 The expected impact on the public sector, charities or voluntary bodies will be an increase in the availability of naloxone and a reduction in fatal opioid overdoses. It is expected that the cost associated with this wider availability, e.g. training and storage, would be minimal.

10.3 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on www.legislation.gov.uk.

Public Health England and the Public Health Agency

10.4 No impact assessments have been produced in relation to Public Health England and the Public Health Agency because the amending regulations are only correcting an oversight.

11. Regulating small business

11.1 The legislation does not apply to small business.

12. Monitoring & review

12.1 The MHRA will carry out reviews of the policies contained in the Human Medicines Regulations 2012 as part of its Regulatory Excellence Programme, which will aim to ensure that the MHRA fully meets better regulation principles. The MHRA will publish the results of these reviews and will consult fully with interested parties on any proposed policy changes.

13. Contact

Anne Ryan at the MHRA Tel: 0203 080 6392 or email: anne.ryan@mhra.gsi.gov.uk can answer any queries regarding the instrument.