EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENT) REGULATIONS 2016

2016 No. 186

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 is laid before Parliament by Command of her Majesty.

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 therapeutic radiographers and supplementary prescribing for registered dietitians;
- extend the list of drugs that midwives are allowed to supply in the course of their professional practice and also to allow registered orthoptists to supply and administer specific medicines; and
- clarify the obligations for wholesale dealing medicines to non-EEA countries as well as the meaning of selling a medicinal product at a distance to the public by means of information society services.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

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

Dietitians, therapeutic radiographers, midwives and orthoptists

4.1 Part 12 and Schedule 17 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.

Distributing medicines to a person in a non-EEA country

4.2 Part 3 of the 2012 Regulations transposes the provisions of Directive 2001/83/EU on the wholesale distribution of medicines. This prohibits a person from distributing a medicinal product by way of wholesale dealing without an appropriate licence and provides that a wholesale dealer's licence does not authorise the distribution of unlicenced medicines unless the medicine is being distributed to a person in a non-EEA country. The obligations that the holder of a wholesale dealer's licence has to comply with, are also set out in Part 3 of the 2012 Regulations. These make it a condition of the licence to not sell or supply unlicenced medicines and so the two areas are being brought together to clarify the obligations of a wholesale dealer when distributing medicines to a person in a non-EEA country.

Online sales of medicines to the public

4.3 Part 12A of the 2012 Regulations transposes the provisions of Directive 2001/83/EU on the online sales of medicines. This instrument amends Part 12A of the 2012 Regulations to provide clarification that any reference to selling a medicinal product at a distance to the public includes supplying and offering to sell or supply a medicinal product to the public. This clarification is considered necessary to prevent the requirements on the online sales of medicines, and the need to register, from being misinterpreted.

5. Extent and Territorial Application

5.1 This instrument extends to all of the United Kingdom.

5.2 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

Dietitians, therapeutic radiographers, orthoptists and midwives

7.1 The instrument permits registered therapeutic radiographers to independently prescribe medicines, including a limited list of controlled drugs, and to mix medicines. It also adds registered dietitians to the list of health professionals who can enter into supplementary prescribing arrangements. The instrument also allows orthoptists to sell and supply certain medicines directly to their patients. Orthoptists investigate, diagnose and treat defects of binocular vision and abnormalities of eye movement. In addition, the instrument further extends the list of medicines that midwives can supply in the course of their professional practice. This is in order to reflect amendments to the Misuse of Drugs Regulations 2001[1] which placed midwives' supply orders for certain controlled drugs on a similar footing to prescriptions. In effect, this changed from a system through which midwives obtained stocks of medicines by making them specific to individual patients.

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

[1] Misuse of Drugs (Amendment No 2) (England.Wales and Scotland) Regulations 2015 SI No 2015/891

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 radiography practice, the exemption is being extended to include therapeutic radiographer independent prescribers.

Miscellaneous

7.4 Separately the MHRA has identified some areas of the 2012 Regulations, relating to the wholesale dealing of medicines to non-EEA countries and the online sale of medicines to the public that are potentially unclear and is taking the opportunity to clarify them. The MHRA is also taking the opportunity to correct some minor omissions relating to podiatrist and physiotherapist independent prescribers. For example, when prescribing for these groups was introduced, they were not included in the definition of "relevant prescriber" or "health prescription" set out in Part 12 of the 2012 Regulations.

Consolidation

7.5 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

Dietitians, therapeutic radiographers, orthoptists and midwives

8.1 NHS England (NHSE) led the consultations on the proposals for dietitians, radiographers and orthoptists 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. There were 464 in response to the dietitians' exercise, 984 for radiographers and 204 for orthoptists. A great majority of the responses supported the proposals.

8.2 The Home Office consulted on the proposals for midwives in 2011 and the vast majority of responses were supportive. .

9. Guidance

9.1 The Health and Care Professions Council and the relevant professional representative bodies will issue guidance on the changes relating to dietitians, orthoptists and therapeutic radiographers. The Department of Health will issue guidance to the healthcare sector on the midwives' amendment.

10. Impact

10.1 The proposals for dietitians, therapeutic radiographers, orthoptists and midwives 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.

10.3 The Reducing Regulation Committee (RRC) has agreed the measure is deregulatory in nature. Impact Assessments are attached to this memorandum. They have not been validated by the Regulatory Policy Committee but represent NHSE's current best estimate of the impact of the proposals. Validation will be sought at a later stage. The RRC has confirmed that this approach complies with the requirements of the Better Regulation Framework, due to the deregulatory nature of the changes and the negligible impact on the independent sector.

10.4 Work is ongoing to finalise the estimates in the Impact Assessments and seek Regulatory Policy Committee validation. The final versions will be published on www.legislation.gov.uk.

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 remaining amendments.