EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENT) REGULATIONS 2017

2017 No. 715

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 allow schools to hold stocks of Adrenaline Auto-Injectors (AAIs) for use in an emergency. They also correct an omission in the 2012 Regulations relating to provisions for orthoptists to sell or supply certain prescription only medicines by requiring that there is an annotation against their names in the relevant register maintained by the Health and Care Professions Council (HCPC) signifying that they are qualified to use the medicines. Finally, the amending Regulations make some minor drafting amendments to the 2012 Regulations to increase the clarity of certain provisions and correct typographical errors.

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

Schools and orthoptists

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 and injectable medicines may only be administered by an appropriate practitioner. An appropriate practitioner includes a doctor, dentist or other independent prescriber. 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 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

Stocks of AAI in Schools

7.1 AAIs are licenced as POMs. This instrument permits schools to obtain stocks of AAIs which can then be administered in an emergency to pupils who are known to require such medication. The benefit of making this change is to reduce the risk of death following anaphylaxis (severe allergic reaction).

7.2 The Anaphylaxis Campaign charity was established to bring together leading organisations in immunology to campaign for the law to be changed to enable schools in the UK to be able to hold AAIs without prescriptions, for use in an emergency. This followed an earlier successful campaign for schools to hold spare emergency asthma inhalers. At the request of the Department of Health, the Anaphylaxis Campaign provided evidence supporting a proposal for changing the law drawing on existing evidence and the results of surveying teachers, parents and health professionals.

7.3 The Commission on Human Medicines (an independent advisory body which advises Ministers on matters relating to safety of medicines) supported the proposal for an amendment to the legislation.

Orthoptists

7.4 The MHRA is taking the opportunity to correct an omission in relation to the provisions allowing orthoptists to sell or supply certain POMs. These were not subject to an intended requirement for there to be an annotation against the name of the orthoptist in the HCPC register signifying that they are qualified to use the medicines.

Miscellaneous

7.5 Separately the MHRA has identified an area of the 2012 Regulations, relating to the import of unlicensed medicinal products to fulfil special patient needs, which is potentially unclear and is taking the opportunity to clarify this. The MHRA is also taking the opportunity to correct some minor typographical errors. For example, in the definition of "external use" it incorrectly refers to "systematic absorption" rather than "systemic absorption".

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

The Department of Health led the consultation on the proposal for allowing schools to hold stocks of AAIs for use in an emergency. It took place during March to May 2017; there were 544 responses, and the overwhelming majority (97% of respondents) supported this change.

8.1 No consultation was carried out in relation to the other amendments as they are simply correcting omissions and making minor clarifications.

9. Guidance

9.1 The Department of Health will issue guidance to schools on the use of AAIs in an emergency, drawing on the best current clinical practice.

10. Impact

10.1 No impact assessment has been produced. The AAI measures are deregulatory and none of the other amendments 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 reducing the risk of death following anaphylaxis.

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: 0203 080 6392 or email: anne.ryan@mhra.gov.uk) can answer any queries regarding the amendments.