EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENT) REGULATIONS 2014

2014 No. 490

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 instrument

2.1 These Regulations amend the Human Medicines Regulations 2012 in order to implement Article 11 of Directive 2011/24/EU and Directive 2012/52/EU on the recognition of prescriptions issued in an EEA State other than the one where the prescription is to be dispensed and the information requirements for such prescriptions. The Regulations also make related and other minor amendments to the Human Medicines Regulations 2012 to clarify or correct the amended provision.

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

3.1 The Human Medicines Regulations 2012 were reported for defective drafting by the House of Lords and the House of Commons Joint Committee on Statutory Instruments ("JCSI") (Committee's 9th Report of Session 2012-13)[1]. In their 11th Report of Session 2013-14[2], the JCSI considered the Human Medicines (Amendment) Regulations 2013 ("the 2013 Regulations). The JCSI noted that the 2013 Regulations did not amend either provision that were reported previously by the Committee, and the Explanatory Memorandum for these Regulations indicated that there were no matters of special interest to the Committee. The JCSI sought an explanation of the omission to mention in the Explanatory Memorandum for the 2013 Regulations details about the decision not to amend the provisions previously reported.

3.2 In its response to the JCSI on the 2013 Regulations, the Department of Health stated that it would review the operation of regulation 3 (which deals with the scope of the regulations) and would have due regard to the JCSI report on regulation 3(9). As regards the Committee's comments concerning Regulation 165, the Department stated that it would keep Part 9 of the Human Medicines Regulations 2012 under review and would consider whether a provision which more explicitly provided that Part 9 was not to be taken as an essential preliminary to other action the licensing authority might take under or by reference to the Regulations would be better. These Regulations amend regulation 165 of Human Medicines Regulations 2012 to clarify the position.

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[1] HL Paper 56/ HC 135-ix.
[2] HL Paper 71/ HC166-xi.

4. Legislative Context

Implementation of Directives

4.1 The Human Medicines Regulations 2012 transpose Directive 2001/83/EC on the Community code relating to medicinal products for human use. These Regulations amend the Human Medicines Regulations 2012 in order to implement European obligations under Directive 2011/24/EU and Directive 2012/52/EU.

4.2 Article 11 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare provides for the recognition of prescriptions issued in another Member State. However, by virtue of paragraph 6 of Article 11 the recognition provision does not apply in relation to medicinal products subject to a 'special medical prescription' as provided for in Article 71(2) of Directive 2001/83/EC. The UK already recognises prescriptions issued in other Member States with the exception of prescriptions in respect of certain controlled drugs. In order to ensure continuity of those provisions it is necessary to designate those controlled drugs as products subject to a special medical prescription in the Human Medicines Regulations.

4.3 The Annex to Commission Implementing Directive 2012/52/EU provides for a non-exhaustive list of elements to be included in medical prescriptions that EEA Member States are obliged to recognise by virtue of Article 11(1) of Directive 2011/24/EU. The amendments being made by these Regulations will ensure that prescriptions from EEA Member States are recognised in the UK if they contain the list of elements. They will also ensure that prescriptions issued in UK that are to be dispensed in another EEA State are required to contain the items on list of elements.

4.4 The House of Commons European Scrutiny Committee and the House of Lords European Union Committee were consulted on the proposed UK negotiating position and kept informed of developments as negotiations on Directive 2011/24/EU progressed. The final text was cleared by both Committees.

4.5 A Transposition Note in relation to implementation of European legislation is in the attached Annex.

Administration of prescription medicines by the armed forces

4.6 Part 12 of the Human Medicines Regulations provides exemptions from the usual requirement that medicines which are for injection (parenteral medicines) if not self-administered, may only be administered by or in accordance with the directions of an appropriate practitioner. An "appropriate practitioner" includes a doctor, dentist and independent nurse and pharmacist prescriber.

4.7 The amendment of Schedule 17 restores the position that existed in legislation that was consolidated into the Human Medicines Regulations 2012

whereby members of Her Majesty's armed forces were permitted to administer parenteral medicines provided in certain specified emergency situations.

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 the negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

What is being done and why

7.1 Directive 2011/24/EU on cross-border healthcare was developed to clarify the law and rights of citizens in relation to accessing healthcare across the EU. The UK considered the Directive to be a positive development. Similarly, the UK supported the establishment of the non-exhaustive list of elements to be included in cross-border prescriptions on the basis that they benefit patient safety and offer more certainty for the dispensing pharmacist.

7.2 The Human Medicines Regulations 2012 already provide that prescriptions issued in another EEA State can be dispensed in the UK provided certain conditions are met. The decision to accept such a prescription is to be subject to the professional judgement of the pharmacist as it is at present.

7.3 However, the current UK provisions do not enable an EEA prescription to be dispensed if it is for a controlled drug specified in Schedules 1, 2 or 3 of the Misuse of Drugs Regulations 2001 or under the equivalent provisions for Northern Ireland. In order to maintain this policy it is necessary to designate such a product as a product subject to a special medical prescription. The cross-border healthcare Directive does not apply to a product subject to a special medical prescription by virtue of Article 11(6) of that Directive.

7.4 The amending Regulations also adopt the non-exhaustive list of elements provided in the Annex to the Commission Implementing Directive 2012/52/EU. The list of elements are required to be included in EEA prescriptions that are to be dispensed in the UK and those being issued in the UK for dispensing in an EEA State. Where such a prescription is issued in the UK, the provisions will only apply in circumstances where the patient specifically requests a prescription to take abroad. In practice, the majority of these elements are already included in prescriptions issued in the UK.

7.5 The amendment relating to the armed forces will restore a provision, originally enacted in 2009, that should have been consolidated in the Human Medicines Regulations 2012 but was omitted in error.

7.6 Regulation 165 of the Human Medicines regulations is being amended to clarify the provision further to the undertaking the Department gave to the JCSI.

Consolidation

8. Consultation Outcome

8.1 As the amendments to legislation are minor and affected specific groups of health professionals, the MHRA carried out an informal targeted consultation exercise. There was only a limited response. One key stakeholder expressed concerns and considered that the requirements were unnecessary. The remaining replies were supportive in principle but sought clarity in relation to certain aspects of the proposals.

8.2 The provision concerning administration of prescription medicines by the Armed Forces restores a provision that was incorrectly not consolidated into the Human Medicines Regulations 2012. The Department consulted on these provisions when they were originally made in 2009[3]. At that time, a three month consultation was undertaken and the MHRA received 12 replies. Nine of these were broadly supportive and the remainder either made no comment or expressed no preference.

9. Guidance

9.1 The MHRA website will be updated to reflect the changes. The MHRA and the Department of Health will consider what supporting guidance may be necessary in discussions with stakeholders.

9.2 The situations in which members of the armed forces can administer medicines will be clearly laid down by the Surgeon General's Department.

10. Impact

10.1 No impact assessments have been produced. The cost burden imposed by the implementation of Directives 2011/24/EU and 2012/52/EU is considered to be very low and the adoption of the "special medical prescription" category of medicinal product has no impact on stakeholders as any practical effects will be dealt with through the Agency's internal administrative systems. At the time the armed forces provisions were originally enacted, they did not impose any cost compliance on business, charities or the voluntary sector.

[3] Medicines (Exemptions and Miscellaneous Amendments) Order 2009/3062, Article 3(3).

11. Regulating small business

11.1 The legislation in relation to implementation of the Directives applies to small business.

12. Monitoring & review

12.1 The Human Medicines Regulations 2012 are subject to a regular review by the Secretary of State. The Human Medicines (Amendment) Regulations 2014 implement Article 11 of Directive 2011/24/EU and Directive 2012/52/EU and other legislative changes are subject to that review.

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.