EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENT) REGULATIONS 2013

2013 No. 1855

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The instrument introduces measures designed to strengthen the medicines supply chain from the threat of counterfeit medicines. There are an increasing number of medicines detected in the European Union which are falsified either as to their identity, their history (documentation) or their source. Such products pose a threat to public health because they contain sub-standard or falsified ingredients, ingredients, including active substances, in the wrong dose or no active ingredient at all.

2.2 The instrument also introduces two offences in relation to pharmacovigilance[1] obligations and introduces independent prescribing for registered physiotherapists and podiatrists.

2.3 The instrument is laid in recess because the Government has failed to transpose Directive 2011/62/EU on time and the Commission has already initiated infraction proceedings against the Government.

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

3.1 None

4. Legislative Context

4.1 Directive 2001/83/EC has been transposed into UK legislation through the Human Medicines Regulations 2012.

4.2 This instrument amends the Human Medicines Regulations 2012 in order to implement -

- the requirements of Directive 2011/62/EU, which amends 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products;
- Commission Implementing Regulation (EU) No 520/2012 of the 19th June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council. The Implementing

[1] Pharmacovigilance is the monitoring of the safety of medicines.

Regulation, which is directly applicable from 10 July 2012, places further (or more detailed) obligations on marketing authorisation holders in relation to pharmacovigilance on top of the obligations already introduced by Directive 2010/84/EU as regards pharmacovigilance which has been transposed through the Human Medicines Regulations 2012. Parliament cleared Directive 2010/84/EU from scrutiny;

- an EU Corrigendum which corrects an error in Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicines for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products.

4.3 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 the European Instruments progressed. The final texts were cleared by both Committees.

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

4.5 Finally, the instrument amends the Human Medicines Regulations by extending independent prescribing to suitably qualified, registered podiatrists and physiotherapists. It also allows independent physiotherapist and podiatrist prescribers to mix medicines.

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*

7.1 This instrument amends the Human Medicines Regulations 2012 in order to implement new provisions introduced by the Falsified Medicines Directive (2011/63/EU) on the sale and supply of medicinal products. Those provisions are designed to strengthen the medicines supply chain from the threat of counterfeit medicines. In particular, the provisions are expected to deal with the problem of an increasing number of medicines detected in the European Union which are falsified either as to their identity, their history (documentation) or their source. Such products either contain sub-standard or falsified ingredients, ingredients or ingredients, including active substances, in

the wrong dosage or sometimes no active ingredient at all thus posing an important threat to public health. Falsified medicines can reach patients through illegal means and via the legal supply chain so in addition to the health risks they may undermine confidence in the healthcare delivery systems in Member States.

7.2 The overall aim of the Falsified Medicines Directive is to strengthen the legal supply chain by increasing the opportunities for identifying and reporting counterfeit medicines found in the supply chain before they reach patients, and also to provide a more robust framework of regulation that will deter counterfeiters from attempting to infiltrate the medicines supply chain. Many of the provisions build on existing obligations on those who trade in medicines (manufacturer's and wholesale dealers) but the legislation also extends regulation to hitherto unregulated operators such as persons engaged in brokering the sale and supply of medicinal products.

7.4 This instrument also makes some amendments to the Human Medicines Regulations in relation to pharmacovigilance matters and prescribing by podiatrists and physiotherapists.

7.5 In relation to pharmacovigilance, as a part the transposition of Directive 2010/84/EU, pharmacovigilance offences were inserted into the Human Medicines Regulations 2012. The Commission Implementing Regulation (EU) No. 520/2012 provides further obligations on marketing authorisation holders in relation to pharmacovigilance on top of the obligations already introduced by Directive 2010/84/EU and this instrument makes the breach of the new obligations a criminal offence. In particular, two new offences in relation to the pharmacovigilance obligations of marketing authorisation holders are introduced. .

7.6 As regards podiatrists and physiotherapists, the instrument permits these practitioners to independently prescribe a limited list of controlled drugs and to mix of medicines. 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 medicines for their patients without the authority of a doctor or dentist. Increasing access to prescribing and medicines supply mechanisms has the potential to improve patient safety and quality of care. It also makes better use of professional skills. 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, nurse independent prescribers and pharmacist independent prescribers to mix or direct others to mix. As mixing of medicines occurs in physiotherapy and podiatric practice, the exemption is being extended to include podiatrist and physiotherapist independent prescribers.

- ***Consolidation***

7. 7 Almost all medicines legislation was consolidated in the Human Medicines Regulations 2012. This is the first amendment to that instrument.

8. Consultation outcome

8.1 A targeted, four-week consultation was held over October/November 2012 seeking views on the proposed approach to transposition of Directive 2011/62/EU and of the impacts of the changes. This shorter timescale was appropriate given the technical and specialised nature of the regulations.

8.2 Forty responses were received[2]; these did not express any concerns with the approach to transposition but they did provide quantitative information that was used to develop the impact assessment.

8.3 As a result of the consultation late 2011 on the transposition of Pharmacovigilance Directive 2010/84/EU[3] the decision was taken to enforce all pharmacovigilance obligations through criminal sanction.

8.4 Separate consultation exercises were held for independent prescribing by podiatrists[4] and physiotherapists[5] between September and December 2011. There were 1,210 replies in response to the podiatrist exercise and 689 for physiotherapists. A great majority of the responses supported the proposals.

9. Guidance

9.1 The MHRA will communicate the changes directly to known stakeholders that will be affected by the changes. The MHRA's website will also be updated to reflect the changes.

10. Impact

10.1 We have estimated the net cost of Directive 2011/62/EU to business per year at £1.891 million. The total costs to the UK from counterfeit medicines are estimated at between £0.775 and £0.915 million per year.

10.2 There is no impact on the public sector.

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

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[2] http://www.mhra.gov.uk/Publications/Consultations/index.htm
[3] http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con172283.pdf
[4] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/156097/Podiatrist-Consultation-Summary.pdf.pdf
[5]https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/156096/Physiotherapist-Consultation-Summary.pdf.pdf

10.4 Impact assessments for the transposition of Directive 2010/84/EU[6] and independent prescribing for registered physiotherapists[7] and podiatrists[8] are also available.

11. Regulating small business

11.1 The legislation applies to small business.

11.2 To minimise the impact of the requirements on firms employing up to 20 people, the approach taken is that a Wholesale Dealer License can be obtained at a reduced fee by firms that generate less than £35,000 through the wholesale of medicines per year.

11.3 This reduced fee is already in place but we expect that there will be a number of small firms that will be covered by the wholesale supply provisions of the Directive that were not covered before.

12. Monitoring & review

12.1 The Human Medicines Regulations 2012 is subject to a regular review by the Secretary of State. The Human Medicines (Amendment) Regulations 2013 make the provisions transposing Directive 2011/62/EU and the other legislative changes subject to that review.

13. Contact

Sandor Beukers at the Medicines and Healthcare products Regulatory Agency (MHRA) Tel: 020 3080 7213 or email: sandor.beukers@mhra.gsi.gov.uk can answer any queries regarding the instrument.

[6] http://www.legislation.gov.uk/ukia/2011/231/pdfs/ukia_20110231.pdf
[7] http://www.legislation.gov.uk/ukia/2011/231/pdfs/ukia_20110231.pdf
[8] https://www.gov.uk/government/publications/proposals-to-introduce-independent-prescribing-by-podiatrists-impact-assessment