EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENT NO. 2) REGULATIONS 2013

2013 No. 2593

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. They do so in order to implement Directive 2012/26/EU and Regulation (EU) No 1027/2012, both as regards pharmacovigilance. (Pharmacovigilance is the monitoring of the safety of medicines.) The Regulations also allow General Sale List (GSL) medicines to be sold on trains and aircraft.

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

3.1. None

4. Legislative Context

4.1. The subject matter of human medicines falls within EU competence. Directive 2001/83/EC and Regulation (EC) No 726/2004 create a comprehensive regime for the authorisation of medicinal products for human use, for the manufacture, import, distribution, sale and supply of those products, for their labelling and advertising, and for pharmacovigilance. They provide for the protection of public health by ensuring that medicines meet appropriate standards of safety, quality and efficacy.

4.2. The Human Medicines Regulations 2012 (the 2012 Regulations) implement Directive 2001/83/EC and Regulation (EC) No 726/2004 in the UK.

<u>Pharmacovigilance changes</u>

4.3. In October 2011, the European Commission proposed a Directive and a Regulation to amend (amongst other things) the pharmacovigilance provision of Directive 2001/83/EC and Regulation (EC) No 726/2004. The Commons and Lords EU Committees were consulted on the proposed UK negotiating position on the proposals and kept informed as negotiations on the Directive progressed. The proposals were cleared by both Committees.

4.4. In October 2012, Directive 2012/26/EU of the European Parliament and of the Council amending Directive 2001/83/EC as regards pharmacovigilance and Regulation (EU) No 1027/2012 of the European Parliament and of the Council amending Regulations (EC) No 726/2004 as regards pharmacovigilance were published in the Official Journal. The Directive and the Regulation make minor procedural changes in relation to (amongst other things) the current pharmacovigilance systems for monitoring the safety of medicines.

4.5. These Regulations amend the 2012 Regulations in order to implement these amendments in the UK.

Sale of General Sale List (GSL) medicines

4.6. The 2012 Regulations provide that GSL medicines can be sold or supplied at retail premises other than a registered pharmacy provided those premises are lockable and the products are pre-packed. There are exemptions from these restrictions which allow for supply of GSL medicines in settings that would not normally be regarded as lockable premises. In particular, GSL medicines can be supplied, but not sold, for the immediate treatment of sick or injured persons on an aircraft. There are no provisions for the sale of medicines on trains.

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

Pharmacovigilance changes

7.1. Following a particular historical medicines safety issue which arose in France, the European Commission undertook a review of EU pharmacovigilance procedures for monitoring of the safety of medicines to ensure that current safeguards were adequate to prevent a recurrence. They made proposals for minor changes to strengthen the new European pharmacovigilance systems mandated under Directive 2001/83/EC so that, if a safety issue is identified in one country, co-ordinated action is taken in all member states where a product is marketed. The UK supported the proposals and considered that their effect did not materially alter the current safeguards in place across Europe.

7.2. Pharmaceutical companies already have a duty under European law to notify the MHRA if they intend to withdraw a product from the UK market. They may also request cancellation of a licence. The only new requirement is that the law will stipulate that the company must include a reason for the action in these notifications.

7.3. There is a new legal requirement to notify the MHRA and give a reason when an application for renewal of a licence is not to be made.

7.4. UK law was clarified in 2008 to place a legal responsibility on companies to notify the MHRA of matters affecting the evaluation of the benefits and risks of a medicine, wherever the information originates from. The new requirement to notify the MHRA if a product is to be withdrawn from the market or a licence is to be withdrawn in a third country on grounds relating to safety therefore makes explicit one of these circumstances when notification to the MHRA is already required.

7.5. The changes will ensure that all member states where a medicine is licensed have the opportunity to consider whether new safety information affects the risk: benefit profile of national products.

Sale of GSL medicines

7.6. As part of the Red Tape Challenge and informal consultation with industry the MHRA agreed to develop proposals to allow GSL medicines to be sold on trains and aircraft. The informal consultation suggested that there may be benefits for public health in that individuals would have increased availability to medicines for example, being able to obtain nicotine replacement products on a long-haul flight or treat minor self-limiting ailments.

7.7. 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

Pharmacovigilance changes

8.1. The MHRA has consulted with the MHRA Medicines Industry Liaison Group which includes ten trade associations representing the whole range of branded prescription and over-the-counter medicines, herbal, homeopathic and generic medicines and pharmacy interests. They endorsed the MHRA's assessment of the impact on businesses and agreed that no significant new cost burden would be added. They have also been consulted on the development of guidance.

8.2. Since the changes to existing legislation were minor and affected only pharmaceutical companies, the MHRA chose to consult them using this targeted consultation framework and did not carry out a formal public consultation.

Sale of GSL medicines

8.3. There was informal consultation with industry. The MHRA also formally consulted with a wide range of interested organisations including health profession regulatory bodies, pharmacy organisations and patient interest groups. The Agency published the consultation letter on its website. As the proposal was considered to be minor, the consultation period was initially four weeks. Because of the limited responses received, this period was extended by two weeks. Thirteen replies were received of which nearly half were from pharmacy bodies. Five responses, including two from individuals, did not support the proposals. This was for various reasons such as medicines already being available for emergency use on planes, the wide availability of GSL medicines from retail premises and limited demand for on-board sales. Four replies were supportive and the remaining four were not specific. The latter group commented on several aspects relating to the proposals including practicalities such as limits to the range of medicines that could be carried on board planes and trains. The majority of responses therefore did not object to the proposals.

9. Guidance

Pharmacovigilance changes

9.1. The EU has published guidance to accompany the new EU legislative provisions on pharmacovigilance to ensure consistent application across the

EU. The MHRA will supplement this guidance if further clarity is requested by marketing authorisation holders.

9.2. The MHRA website will be updated to reflect the changes. All guidance documents will be available on the MHRA website.

Sale of GSL medicines

9.3. The MHRA website will be updated to reflect the changes. The MHRA will provide supplementary guidance if necessary.

10. Impact

10.1. No impact assessment has been produced. The cost burden imposed by the implementation of Directive 2012/26/EU is considered to be very low and the GSL sale measures are deregulatory.

11. Regulating small business

11.1. The legislation applies to small business.

11.2. There is no scope for exempting small businesses from the pharmacovigilance provisions in Directive 2012/26/EU, as EU medicines legislation is based on the principle that harmonised requirements applying to all medicines in all Member States provides the basis for free movement of medicines throughout the EU. Any exemption from these provisions would be contrary to EU law.

12. Monitoring & review

12.1. In accordance with the Government guidance on sunsetting, the Regulations ensure that the provisions implementing Directive 2012/26/EU will be subject to a review within five years of the new Regulations coming into force.

12.2. 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

Pharmacovigilance changes

Beryl Keeley at the MHRA (beryl.keeley@mhra.gsi.gov.uk or telephone 020 3080 6765) can answer any queries regarding these aspects of the instrument.

Sale of GSL medicines

Anne Ryan at the MHRA (anne.ryan@mhra.gsi.gov.uk or telephone 0203 080 6392) can answer any queries on the GSL changes.