EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENT) (NO. 2) REGULATIONS 2014

2014 No. 1878

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 insert provisions in relation to parallel import licences which were omitted when regulations were consolidated by the 2012 Regulations. The Regulations also allow schools to hold stocks of inhalers containing Salbutamol for use in an emergency and they amend provisions in relation to the recognition of prescriptions issued by healthcare professionals in EEA states so that it is clear that those provisions also apply to prescriptions issued in Switzerland. Finally, they simplify the information requirements that apply to advertisements for medicines aimed at healthcare professionals and other suppliers of medicines.

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

3.1. None.

4. Legislative background

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 (safety monitoring). 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.

4.3. The 2012 Regulations consolidated provisions previously included in the Medicines Act 1968 and various Statutory Instruments. Part 5 of the 2012 Regulations deals with marketing authorisations and is intended to include provisions in relation to parallel import licences which are a type of marketing authorisation. Unfortunately, provisions for parallel import licenses have not been adequately made in the 2012 Regulations so that it is not clear for example that such licences can be varied, suspended or revoked. These Regulations rectify those deficiencies.

4.4. Part 12 of the 2012 Regulations deals with medicinal products. Inhalers containing Salbutamol are licensed as prescription only medicines (POMs)

and are not available for supply in schools under the current provisions in Part 12 and Schedule 17 of the 2012 Regulations.

4.5. The Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008 (S.I. 2008/1692) provided for the recognition of prescriptions issued by EEA health professionals. In those Regulations it was clear that the provisions would also apply to health professionals from Switzerland but this aspect was less clear after those Regulations were consolidated into the 2012 Regulations and although subsequently amended, the position is not entirely clear.

4.6. Part 13 of the 2012 Regulations deals with information to be included on packaging and package leaflets for medicines. In particular Schedule 27 (read with regulation 260) sets out the information that must be included in the patient information leaflet that is supplied in the medicine pack.

4.7. Part 14 of the 2012 Regulations deals with the advertising of medicines. In particular, Chapter 2 of Part 14 sets out requirements that advertisements for medicines must meet, including specific information that must be provided in advertisements to prescribers and suppliers of medicines. There are separate requirements in Chapter 2 of Part 14 for advertising aimed at the public and these are unaffected by these Regulations.

4.8. These Regulations amend the 2012 Regulations to:

- insert and clarify the requirements in relation to parallel import licences that were not included when the 2012 Regulations were made including requirements for the approval, variation, suspension or revocation of such licences;
- allow schools to hold stocks of inhalers containing Salbutamol for emergency use;
- make it clear that prescriptions issued by Swiss health professionals may be dispensed in the UK;
- amend the information that needs to be included in advertisements for medicines aimed at persons able to prescribe or supply such medicines. These requirements are set out in regulations 294 and 295 and schedule 30;
- make minor corrections to the information required to be included in the patient information leaflet as set out in Schedule 27.

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

Parallel import licences

7.1. The consolidation of the previous provisions into the 2012 Regulations did not make it clear how the 2012 Regulations would apply to parallel import licences although such licences are a type of marketing authorisation. Consequently, conditions and requirements essential for patient safety were omitted and it was not clear, for example, if there was a power to vary suspend or revoke parallel import licences. These Regulations rectify the position so that the conditions and requirements in relation to such licences are clearly set out in the Regulations.

Inhalers containing Salbutamol

7.2. In 2012, the charity Asthma UK approached the Department of Health to ask if the law could be amended to allow schools to keep a spare inhaler for use in an emergency. Following an evaluation of the risks and benefits and advice from the Commission on Human Medicines (an independent advisory body which advises Ministers on matters relating to safety of medicines), the Department of Health supported the proposal to reduce deaths and distress from asthma. These Regulations will allow schools to hold stocks of inhalers containing Salbutamol for use in an emergency.

EEA health professionals

7.3. When the 2012 Regulations consolidated provisions on the recognition of prescriptions issued by EEA health professionals they did not clearly make provision for recognition of Swiss prescriptions on the same basis. The position was not fully rectified when these provisions were subsequently amended. The amendments in these Regulations will restore the effect of provisions to the position that existed under the pre-consolidated Regulations.

Advertising changes

7.4. Prescribers and suppliers of medicines need objective information on the licenced use of a medicine in order to be able to evaluate advertising claims and make decisions on prescribing or supply. For this reason, it is a statutory requirement that the certain information (known as the "prescribing information") is included in advertisements for medicines and this information is found in the 'small print'. Prescribing information includes information on adverse reactions, precautions, contra-indications and methods of use. The same information requirements currently apply when advertising a new prescription only medicine to doctors as when advertising a medicine available on general sale to supermarket buyers.

7.5. A 'short form advertisement' format with reduced 'small print' is currently permitted, but only for small size advertisements in journals and similar publications. For a short form advertisement, the prescribing information is replaced by a statement that "Information about this product, including

adverse reactions, precautions, contra-indications, and method of use can be found at:" followed by an appropriate web site address."

7.6. The over-the-counter (OTC) medicines trade association, the Proprietary Association of Great Britain (PAGB) suggested – under the auspices of MHRA's Red Tape Challenge – that information requirements for advertising of OTC medicines for sale without a prescription were simplified. Specifically, they proposed that prescribing information could be replaced by a reference to the availability of this information in the Summary of Product Characteristics (the statutory information about the licensed use of a medicine – the SPC) on a suitable website. The changes were designed to reduce the administrative and cost burden to industry to keep their advertisements current.

7.7. The MHRA accepted this suggestion and these regulations extend the use of the short form advertisement format to all advertisements for OTC medicines aimed at prescribers or suppliers. This is achieved through amendment to regulation 294 of the 2012 Regulations.

7.8. The use of short form advertisments will be limited in practice in two ways. First, by industry codes of practice which will, for example, preclude the use of short form advertisements for advertising of OTC product where they are to be prescribed. Secondly, by the terms of a medicine's marketing authorisation which may preclude the use of short form advertisements, for example, in relation to an innovative 'pharmacy only' medicine at the time of launch.

7.9. The MHRA also accepted a second suggestion to enable advertisements in digital media to include a direct link to the SPC in place of the prescribing information. These Regulations amend Schedule 30 to the 2012 Regulations to enable advertisements to include relevant entries from the medicine's Summary of Product CharacteristicsSPC as an alternative to a summary of those entries.

Product information change

7.10. The information that must appear on the package leaflets that accompany medicines is set out in Directive 2001/83/EC and has been transposed by Regulation 260 of, and Schedule 27 to, the 2012 Regulations. There are two proposals in relation to that text. The first is to correct a transposition error: paragraph 13 of Schedule 27 includes the mandatory text: "This medicinal product is subject to additional *safety* monitoring" but the word "safety" does not appear in the equivalent provision in Directive 2001/83/EU and should be removed. Secondly, paragraph 15 of Schedule 27 needs updating as the text it mandates is not in line with that in EU guidance. A cross reference to Directive 2001/83/EC is to be adopted instead as this will ensure the provision does not fall out of line with the EU position in the future.

Consolidation

7.11. 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

Parallel import licences

8.1. No consultation was carried out. The amendments restore conditions and powers unintentionally omitted from the 2012 Regulations.

Inhalers containing Salbutamol

8.2. Prior to the formal consultation, the Department of Health convened a small working group comprising Asthma UK, DfE and respiratory clinicians, some of whom represented the British Thoracic Society to discuss how best to support schools in using an emergency inhaler, and in particular, to develop clinically appropriate guidance. Formally, the MHRA and the UK Health Departments jointly consulted interested organisations. The consultation letter was also published on the MHRA website. Over 4000 responses were received to the consultation – the bulk as signatories to a petition – and there was unanimous support for making the change to regulations to allow schools to hold their own salbutamol inhaler. Respondents included school and respiratory nurses, clinical commissioning groups, Asthma UK, National Association of Schoolmasters Union of Women Teachers, pharmacists, schools, and consultants, as well as the parents of children with asthma. A number of respondents highlighted the need for the change, based on experience in schools.

8.3. Detailed comments were received from some respondents on the guidance on the use of the inhaler. Particular concerns included the role of the teacher, the number of designated members of staff and their training, the procedure for securing and checking consent and how schools could obtain inhalers, and the Department of Health will work to refine the guidance to take account of these.

EEA health professionals

8.4. No consultation was carried out. This is a minor amendment intended to restore the position in relation to recognition of prescriptions issued by Swiss healthcare professionals.

Advertising changes

8.5. The MHRA consulted with PAGB and the Association of the British Pharmaceutical Industry (ABPI), representing research-based companies marketing prescription medicines, in developing proposals for consultation. The MHRA published a consultation on detailed proposals in February 2014 and wrote to bodies representing doctors, pharmacists and other healthcare professionals and the pharmaceutical industry to invite their comments. The proposals also received coverage in the main pharmacy journals. Sixteen responses were received, including seven from healthcare professional and NHS bodies, four from trade associations and industry self-regulatory bodies, four from pharmaceutical companies and one from a regulatory consultant.

8.6. All respondents who commented agreed that the short form of advertisement was suitable for GSL products and that the full SPC could be provided instead of a summary. The proposal to use short form advertisements for P medicines was supported by industry but views were more mixed among healthcare professionals. The main pharmacy body, two NHS pharmacy responses and one medical body were supportive but two bodies, representing pharmacists and GPs, had concerns about access to information for staff in training and pharmacy staff in general.

8.7. These concerns are addressed by non-legislative safeguards. The MHRA will use the marketing authorisation and self-regulation to require that the short form of advertisement is not used for innovative medicines for the first two years after launch. This will ensure pharmacy staff have the opportunity to gain familiarity with the product. The MHRA has also gained agreement from PAGB to include a requirement that their Code of Practice will require that training materials always carry the full prescribing information.

Product information changes

8.8. As the changes made by these Regulations make minor corrections to the requirements, no consultation was carried out.

9. Guidance

Parallel import licences

9.1. The amendments are restoring unintentionally omitted powers so no guidance is required.

Inhalers containing Salbutamol

9.2. The Department of Health has developed non-statutory guidance with relevant stakeholders to support schools' use of inhalers. This was also consulted on publicly, and the Department will update the guidance in the light of comments received from the consultation and quality assure through further discussions with stakeholders.

EEA health professionals

9.3. MHRA will update the relevant pharmacy professional bodies.

Advertising changes:

9.4. The Agency has updated its advertising guidance (the Blue Guide, Advertising and promotion of medicines in the UK) to reflect these changes. This will be published on the MHRA website before these Regulations come into force. The MHRA is also working with the relevant self-regulatory bodies to ensure their Codes of Practice are updated similarly and that non-legislative controls are in place.

Product information changes:

9.5. Current UK and European guidance already correctly advises companies and no updates are required.

10. Impact

10.1. No impact assessment has been produced. The amendments relating to parallel import licences represent no change. The advertising and asthma measures are deregulatory. The amendment relating to EEA health professionals only clarifies the existing legal position.

11. Regulating small business

11.1. The legislation applies to small business.

11.2. The advertising changes are deregulatory and the benefits will be available to all companies who advertise medicines. The asthma changes are also deregulatory.

12. Monitoring & review

12.1. The MHRA keeps policies contained in the Human Medicines Regulations 2012 as part of its Regulatory Excellence programme. The programme heps the Agency manage its regulatory business, including overseeing its contribution to better regulation initiatives.

12.2. The Agency has also established a Medicines Liaison Group, an industry forum to help ensure the regulatory programme is on track and performing. It is also a helpful means for testing new and emerging ideas for modifying policy or regulation.

13. Contact

Parallel import licences

David Guest at the MHRA (david.guest@mhra.gsi.gov.uk or telephone 020 3080 6672) can answer any queries on these changes.

Asthma inhalers and EEA prescribers

Anne Ryan at the MHRA (anne.ryan@mhra.gsi.gov.uk or telephone 020 3080 6392) can answer any queries on these changes.

Advertising and product information 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.