EXPLANATORY MEMORANDUM TO

THE MEDICINAL PRODUCTS (HERBAL REMEDIES) (AMENDMENT) REGULATIONS 2011

2011 No. 915

1 This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA) and is laid before Parliament by Command of Her Majesty.

2 Purpose of the instrument

2.1 These Regulations repeal section 12(2) of the Medicines Act 1968 ("the Act") which provides an exemption (from the requirement to comply with the restrictions set out in sections 7 and 8 of the Act) for the manufacture, sale or supply of herbal remedies where the process to which the plant or plants are subjected consists only of drying, crushing or comminuting and certain other specified conditions are met. With effect from 30th April 2011, this exemption is incompatible with EU legal provisions set out in Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L No 311, 28.11.2001, p.67) and Directive 2004/24/EC of the European Parliament and of the Council as regards traditional herbal medicinal products (OJ L No 136, 30.04.04, p.85).

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

3.1 None

4 Legislative Context

4.1 These Regulations repeal section 12(2) of the Medicines Act 1968 (as amended) (SI 1968 c.67) ("the Act"). Section 12(2) of the Act is an exemption, from a number of the provisions of the Act, for herbal remedies that was available in domestic legislation prior to the creation of the European Directive on Medicinal Products (2001/83/EC). Directive 2001/83 EC has been amended by Directive 2004/24/EC ("the 2004 Directive"). Section 12(2) of the Act is being revoked to give full effect to this amending Directive.

4.2 The 2004 Directive was established to provide a simplified regulatory approval process for a category of herbal medicinal products that otherwise fall under 2001/83/EC. Accordingly a product can no longer claim an exemption from the requirements of Directive 2001/83/EC or the 2004 Directive simply on the basis of section 12(2). Section 12(2) allows the manufacture, sale or supply of (unlicensed) herbal remedies (other than by personal consultation) where - i) the process to which the plant or plants are subjected consists only of drying, crushing

or comminuting; ii) the remedy is sold without any written recommendation as to its use; and iii) the remedy is sold under a designation which only specifies the plant(s) and the process, and does not apply any other name to the remedy.

5 Territorial Extent and Application

5.1 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, no statement is required.

7 Policy background

- What is being done and why

7.1 The 2004 Directive was established to provide a simplified regulatory approval process for herbal medicines as an alternative to a marketing authorisation (MA); it amended the principal European legislation governing the placing of medicines on the market, Directive 2001/83. The 2004 Directive included provisions enabling the provision of transitional protection of up seven years to products legally on the market at 30 April 2004.

7.2 The 2004 Directive was implemented via Statutory Instrument 2005 No. 2750: The Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 ("the 2005 Regulations" which introduced the traditional herbal registration (THR) scheme. Schedule 6[1] of the 2005 Regulations contained transitional provisions that make it clear that until 30 April 2011, the provisions of the 2005 Regulations did not apply to products that were legally on the UK market on 30 April 2004 by virtue of section 12(2) of the Act.

7.3 While not explicitly revoking section 12(2) of the Act 1968 the 2005 Regulations makes clear that THR requirements would take full effect as of 30 April 2011. In addition, the MHRA consultation document MLX 325 indicated that the Agency would at some point take action explicitly to revoke section 12(2).

8 Consultation outcome

8.1 Formal public consultations in 2002 and 2005 were carried out on the introduction and transposition of the 2004 Directive. This included consideration of the transitional arrangements and the impact of removing section 12(2) on the herbal sector. Since the introduction and transposition of the 2004 Directive, the MHRA have maintained ongoing discussions with the industry's Herbal Forum on all

[1] "The provisions of these Regulations shall not apply until 30 April 2011 to herbal medicinal products which were on the market in the United Kingdom on 30th April 2004 without a marketing authorisation by virtue of section 12(2) of the Act."

aspects of the Directive's implementation, including the ending of the transitional period and the provision of guidance to the sector.

8.2 A further 12 week consultation specifically covering proposals for the revocation of section 12(2) was carried out between October 2010 and January 2011.

8.3 In response to the most recent consultation on the revocation of section 12(2), 69 responses were received from the herbal sector (e.g. industry and practitioner representatives) and from other interested parties.

8.4 A large proportion of the specific comments received related to issues outside the scope of the consultation and of the specific proposal made. Many respondents made broader comments about the Directive itself and made wider comments relating to its transposition. Of those responding to the consultation proposals, the majority acknowledged the need to revoke section 12(2), but express concern about the impact this would have on the range of products herbal practitioner's where able to access. They also stressed the need for practitioner regulation to be put in place. Responses on this issue were made prior to the Government announcement on 16 February 2011 of its intention to regulate practitioners.

9 Guidance

9.1 Guidance on the transitional arrangements provided for within the 2005 Regulations and updated to reflect issues relating to the end of the transition period has been issued via the MHRA website at the following link: http://www.mhra.gov.uk/home/groups/es-herbal/documents/websiteresources/con009362.pdf

10 Impact

10.1 An impact assessment was carried out and consulted on alongside the introduction of 2005 Regulations. The revocation of section 12(2) does not impose any costs or requirements additional to those previously considered within the original impact assessment. The revocation simply serves to clarify and confirm the existing legal position applying from 30 April 2011, i.e. that it is no longer possible to place manufactured unlicensed herbal medicines on the market without an MA or THR. Therefore, a new impact assessment was not deemed necessary. A copy of the final impact assessment which accompanied the Explanatory Memorandum to the Medicines (Traditional Herbal Medicinal products for Human Use) Regulations 2005 can be accessed via the following link: http://www.legislation.gov.uk/uksi/2005/2750/pdfs/uksiem_20052750_en.pdf

11 Regulating small business

11.1 A significant proportion of the businesses affected by the Directive are micro, small or medium sized enterprises. This instrument does not impose any additional requirements to those put in place by the 2005 Regulations. The impact on small

business was fully considered within the impact assessment accompanying the 2005 Regulations.

12 Monitoring & review

12.1 The MHRA published a monitoring framework for the THR scheme in 2009. The MHRA also submitted a response in 2007 to the European Commission's review of the early operation of the Directive, and encouraged the UK herbal sector to do likewise. The MHRA maintains ongoing dialogue with the herbal sector on any emerging issues concerning the implementation of the Directive via the industry's Herbal Forum.

13 Contact

13.1 Andrea Farmer at the Medicines and Healthcare products Regulatory Agency Tel: 020 3080 6404 or email: andrea.farmer@mhra.gsi.gov.uk can answer any queries regarding the instrument.