Medicines and Healthcare Products Regulatory Agency

To: Herbal Interest Groups

Date: 09 July 2013
Our ref HMSTCON13

Ref: PROPOSAL TO END THE "SELL THROUGH" OF UNLICENSED PRODUCTS HERBAL MEDICINES

Dear Sir/Madam

Introduction

1. I am writing to seek your views on our proposal to end the period of grace which allowed retail businesses to sell through existing legally held stocks of manufactured unlicensed herbal medicines, at the end of the transitional protection under EU herbals Directive.

The proposal

2. The proposal is that the MHRA will issue revised guidance to the effect that "sell through" of unlicensed manufactured herbal medicinal products that were already lawfully on the market at the end of the transitional period under the herbals Directive (30 April 2011) will not be allowed to be sold or supplied beyond 31 December 2013.

Application to England, Wales, Scotland and Northern Ireland

3. This consultation is being made available in Wales, Scotland and Northern Ireland. The proposed changes would apply throughout the United Kingdom.

Current position

4. The 2004 EU Directive on traditional herbal medicinal products served to confirm that manufactured herbal medicines on the market require a suitable product licence. This could be either the simplified form of licence – the traditional herbal registration ("THR") introduced by the Directive - or a full marketing authorisation. The Directive permitted transitional arrangements until 30 April 2011 for products that were lawfully on national markets in 2004. In the UK, the Directive was transposed by The Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, S.I.2750**.**

5. At the time the Agency considered that there could have been a significant adverse impact on businesses and disruption within the herbal sector had we insisted that retail shelves be cleared of unlicensed herbal medicines on 30 April 2011. Therefore, before the end of the transition period (August 2010) the Agency updated guidance on the transitional arrangements to indicate that stocks of products that were already legally on the market in retail before 30 April 2011 would not need to be recalled. The existing guidance can be found here: http://www.mhra.gov.uk/home/groups/es-herbal/documents/websiteresources/con009362.pdf

6. The Guidance also confirmed that an offence (relating to placing a medicinal product on the market without the necessary MA or THR) would be committed if a company (manufacturer, wholesaler or importer) placed further stocks of such products on the market after 30 April

2011.

Reasons for proposal to end sell through

7. We propose to end sell through for the following reasons:

- The 2004 herbals Directive was designed to deliver specific benefits for the consumer – with traditional over-the-counter herbal medicines made to assured standards of safety and quality and accompanied by systematic information about safe use of the product; achievement of these benefits is held back if there is a prolonged period of sell through of unlicensed products that do not meet any set standards
- Even allowing for the recognised challenge for smaller companies, inexperienced in medicines regulation, bringing products into the traditional herbal registration (THR) scheme there has been an extensive period of time for companies to make their preparations where this was their intention. The MHRA has provided a significant amount of help to companies seeking to bring their products into the THR scheme
- We now have in excess of 300 products covering over 100 different herbs registered under the THR scheme – clearly demonstrating what is possible
- Although sell through has proceeded well in much of the herbal sector we are concerned at what seems to be a degree of abuse in other parts of the sector with examples of unlicensed herbal products claiming what appear to be implausibly long shelf lives – far longer than are typically agreed for regulated products
- Linked to this is the continuing evidence of poor standards from unlicensed products apparently on sell through which put public health at risk. For example, the Agency has evidence of products containing species differing from the label and non-compliance with voluntary warning labelling agreed with the trade associations
- Some of the herbals concerned, such as St John's Wort and Black Cohosh, have a significant effect on the body and have known side effects or interactions with other medicines, therefore making the provision of reliable product information of particular importance
- There is likely adverse regulatory impact on responsible companies who have invested in meeting the standards of the THR scheme. Their products are at risk of being undercut by unlicensed products which do not meet these standards. Moreover, there is risk that products lacking appropriate safety and warning information for users may actually and erroneously appear safer to consumers than regulated products.

Impact assessment

8. The Agency considers that the proposals contained in this current consultation document will have little substantive adverse impact on operators who are selling through herbal products. This is because, the proposed end date, of 31 December 2013, will have allowed a period of almost three years beyond the date specified by Directive 2004/24 for the sell through of stock lawfully held at April 2011. Overall, we consider that the proposal has no new significant effect on the sector and will not impose any additional costs or have any effect on issues of equality. Conversely, however, the end of sell through will address the risk of unfair competition to responsible operators.

9. Similarly, the proposal does not impose any additional regulatory or financial burdens on the public sector. An impact assessment was produced alongside the regulations putting the Traditional Herbal Registration scheme in place – this can be found in consultation document MLX325. http://www.mhra.gov.uk/home/groups/pl- p/documents/publication/con2022468.pdf

10. We do not believe that the proposal in this consultation will have any adverse effect on any equality issue. We would welcome information on any instances where you believe that there will - or could be - any adverse affect on equality issues under any of the following:

Competition Assessment
Small Firms Impact Test
Legal Aid
Sustainable Development
Carbon Assessment
Other Environment
Health Impact Assessment

Race Equality
Disability Equality
Gender Equality
Human Rights
Rural Proofing

Comments

11. **We would welcome views on the proposal.** If you have concerns about completing sell through by December 2013 we should be grateful for the following information;
    - **a)** What are the products and what are the current levels of stocks remaining to be sold
    - **b)** given normal turn over of stock when you would anticipate that this stock would be sold through
    - **c)** what is the demonstrable evidence (in particular systematic stability data) to support stated shelf-life of products beyond December 2013.

How to respond

12. I would be grateful if any comments in response to this letter could be emailed to: thmrsqueries@mhra.gsi.gov.uk alternatively they may be addressed to: Andrea Farmer, Policy, Government and Corporate Divison, Medicines and Healthcare Products Regulatory Agency, 5th Floor, 151 Buckingham Palace Road, London SW1W 9SZ. Comments must arrive no later than **6 September 2013.** Comments received after this date will not be taken into account.

Circulation of proposals

13. This consultation letter is being brought to the attention of those organisations listed at Annex A. Copies of the consultation are also available from our website - www.mhra.gov.uk and replies are welcome from all interested parties.

14. This consultation abides by consultation criteria set out in the revised Code of Practice on Consultation published by the Department for Business Innovation & Skills and viewable in full via
http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44420.html

Responses: Confidentiality and Disclaimer

15. The information you send us may be passed to colleagues within the Government or related agencies. Furthermore, information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes. These are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004.

16. If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on us.

17. Please ensure that your response is marked clearly, if you wish your response (whole or in part) and name to be kept confidential. Confidential responses will be included in any statistical summary of numbers of comments received and summary of views expressed.

18. The Agency's Information Centre at 151 Buckingham Palace Road will supply copies on request. An administrative charge, to cover the cost of photocopying and postage, may be applied. Alternatively, personal callers can inspect replies at the Information Centre by prior appointment (telephone 0203080 6351).

Andrea Farmer
Senior Policy Manager,
Government, Policy and Corporate Division,
5th Floor, 151 Buckingham Palace Road
London SW1W 9SZ.

CONSULTATION LIST

NB: this list is not intended to be exhaustive. Copies of the consultation are also available from our website - www.mhra.gov.uk – and replies are welcome from all interested parties.

A Nelson & Co Ltd
Acumedic Ltd
Agriculture and Horticulture Development Board (AHDB)
Ainsworths
Alliance Boots
Alliance for Natural Health
Alliance for Natural Health International
American Herbal Products Association
Andean Medicine Centre Ltd
Anglo-Chinese Medicine Doctor Society
Aromatherapy Trade Council (ATC)
Asante Academy of Herbal Medicine
Association of Traditional Chinese Medicine (ATCM)
Ayervedic Company of Great Britain
Ayurveda UK Foundation
Ayurvedic Practitioners Association
Ayurvedic Trade Association
Balance Healthcare Ltd Kingham Herb & Tinctures
Beijing Tong Ren Tang (UK) Ltd
Bioforce (UK) Ltd
BIO-HEALTH LIMITED
Blue Sky Botanics
British Association of Accredited Ayurvedic Practitioners (BAAAP), The
British Association of Flower Essence Producers, The
British Association of Nutritional Therapies (BANT)
British Association of Traditional Tibetan Medicine
British Complementary Medicines Association
British Generic Manufacturers Association (BGMA), The
British Geriatric Society
British Herb Trade Association
British Herbal Medical Association (BHMA)
British Retail Consortium
British Society of Chinese Medicine
Brunel Healthcare Manufacturing Ltd
CAMedica
CCCPH
Centre for Pharmacognosy and Phytotherapy
China Chamber of Commerce for Import & Export of Medicines & Health Products
China European Ltd/Everwell chinese Medical Centre Ltd
Chinese Institute of Herbal Medicine, The
Chinese Medical Institute & Register
Chinese Medicine Association of Suppliers (CMAS)
Chineseherb (UK) Ltd
College of Practitioners of Phytotherapy
Community Pharmacy Magazine
Community Services Pharmacists Group
Company Chemists Association
Consumers Association
Consumers for Health Choice
CTPA Ltd.
European Herbal and Traditional Medicine Practitioners Association (EHPA)
General Pharmaceutical Council (GPhC)

Global Regulatory Services
Greatwall Ltd
Guy's Hospital
Health Food Business Magazine
Health Food Institute
Health Food Manufacturers Association (HFMA)
Herb Society, The
Herbal Apothecary Ltd.
Herbal One TCM Ltd
Herbal Forum
Herbprime Co Ltd
Herbs Hands Healing
Holland and Barrett
Independent Healthcare Advisory Services
Institute of Medical Herbalists
Institute for Complementary and Natural Medicine, The
Institute for Optimum Nutrition
Internal Holistic Aromatherapy Foundation
International Ayurveda Foundation
International Register of Consultant Herbalists and Homeopaths, The
International Society of Professional Aromatherapists
Lloyds Pharmacy
Mayway (UK) Co Ltd
National Institute of Medical Herbalists
National Pharmaceutical Association
Natural Medicines Manufacturers Association (NMMA)
New Medicine Group
Number One Herb Company Ltd
NutrigenomX Consultancy
Office of Complementary Medicines
Only Natural Products
Organic Herb Trading Company, The
Oxford Medical Supplies Ltd
Panacea Health Limited
Pavilion Healthcare International Ltd
Phytomed Medicinal Herbs Ltd
Postlethwaite's Herbal Products
Potters Herbal medicines
Proprietary Association of Great Britain, The (PAGB)
Pukka Herbs
Qin Dynasty Ltd
Register of Chinese Herbal Medicine
Royal Botanical Gardens, Kew
Royal College of Phycisians
Royal College of Psychiatrists
Royal Pharmaceutical Society of Great Britain (RPSGB)
School of Pharmacy
Schwabe Pharma (UK) Ltd
Shanghai Herbs Group Ltd (UK)
Sinolinx (UK) Ltd
Society for the Promotion of Nutritional Therapy (SPNT)
Solgar
Superdragon TM Ltd
Traditional Herbal Medicine Producers
Unified Register of Herbal Practitioners
United Herbs Ltd