Medicines and Healthcare Products Regulatory Agency

To: Interested Organisations

Date 24 February 2014
Our reference: **MLX 384**

PROPOSALS FOR AMENDMENTS TO MEDICINES LEGISLATION TO SIMPLIFY THE INFORMATION REQURED TO BE INCLUDED IN SOME ADVERTISEMENTS TO PRESCRIBERS AND SUPPLIERS OF MEDICINES

Dear Sir/Madam

Introduction

1. We are writing to consult you about a proposal to simplify the information requirements for advertising of medicinal products to prescribers and suppliers of medicines. It is proposed to increase the number of cases where an advertisement for a medicine can include a pointer to where to find detailed prescribing information, rather than the information itself being included it in the advertisement.

2. This change only affects advertising directed at healthcare professionals and other medicines retailers. No changes are proposed to the requirements for advertising to the public.

3. The consultation will help to inform a final decision on the proposal. Any change would be achieved by amendments to the Human Medicines Regulations 2012.

Application to England, Wales, Scotland and Northern Ireland

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

Background

5. 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. Some of this information has to be included in the 'small print' in advertising.

6. Article 91 of Directive 2001/83/EC requires advertisements aimed at prescribers and suppliers of medicines to include "essential information compatible with the summary of product characteristics" (SPC). UK law defines this as a succinct summary of the information in the SPC on indication for use, dosage, contraindications, safety precautions and side effects. This is commonly known as the 'prescribing information'. It typically appears as a section of small print across the lower part of a journal advertisement or on the back page of mailings and other items.

7. The same prescribing information content and level of detail is legally required to be included in advertising to all prescribers and suppliers of medicines. The same requirements apply to an advertisement to doctors for a new prescription only medicine as to an advertisement to supermarket buyers for a medicine available on general sale.

8. An 'abbreviated advertisement' format is currently permitted, but only for small size advertisements in journals and similar publications. 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 [web site address]".

9. Full details of the UK legal requirements for information to be included in advertisements to prescribers and suppliers of medicines are provided in Annex 1.

10. Industry incurs significant costs in updating and reprinting advertising when there is a change to the prescribing information. This may be caused by, for example, an updated safety warning following action taken by the MHRA on reports of adverse reactions observed during safety monitoring of a new medicine.

Proposals

11. These proposals arise from suggestions put forward in the MHRA medicines Red Tape Challenge in 2012 by the over-the-counter (OTC) medicines trade association, the Proprietary Association of Great Britain (PAGB). MHRA has subsequently held informal discussions about the proposals with PAGB and with the Association of the British Pharmaceutical Industry (ABPI), representing research-based companies marketing prescription medicines.

12. The Red Tape Challenge proposals suggested additional circumstances where the abbreviated advertisement format may be suitable for use. The changes are designed to reduce the administrative and cost burden to industry to keep their advertisements current. Informal consultation replies have suggested that the industry expects to make savings as a result of the proposal.

13. MHRA has agreed to consult on proposals to allow increased use of the abbreviated advertisement format for advertising to prescribers and suppliers of medicines. We are particularly interested to hear from healthcare professionals and other medicines retailers about whether you are content with the proposals and how you consider they will affect your ability to access information on the medicines being promoted.

14. We are consulting on three options put forward by industry as follows:

A. Extension of the use of abbreviated advertisement format to all general sale list (GSL) medicines.

15. Medicinal products on general sale have been classified as GSL by the MHRA because they can with reasonable safety be sold without the supervision of a pharmacist. Retailers of these products are not required to have specialist knowledge of the medicines they supply. It may therefore be sufficient to include a pointer to a website

where the full SPC information can be found if needed as described in paragraph 8 above, rather than including the prescribing information. This would apply to the whole range of products on the general sales list including traditional herbal and homeopathic remedies.

Question 1 – Do you agree with the proposal to permit all GSL product advertising to use an abbreviated format? If not, please give your reasons.

B. Extension of the use of the abbreviated advertisement format to medicines that have been on retail sale through pharmacies for a minimum defined period.

16. When a product first becomes available for sale through pharmacies as a Pharmacy medicine, there is a need for education of pharmacy staff in the licensed use of the product but this may lessen as pharmacists and their staff become familiar with the OTC use of the product. It is proposed that after a minimum period of time abbreviated information would be appropriate. The MHRA is minded to set the minimum time period as two years but seeks views in this consultation.

17. In all cases the advertisement would be required to contain a pointer to a website where the full SPC information about the product can be found, as set out in paragraph 8 above. Advertisers would also retain the option to issue a full advertisement if they chose.

Question 2 – Do you agree with this proposal? If not, please give your reasons.

Question 3 – What is the minimum period an ingredient must have been available OTC for before the abbreviated format of advertisement can be used?

18. If this proposal is accepted, MHRA's preferred means of implementation is to set out in legislation that use of the abbreviated format is permitted and then apply the minimum period as one of the risk minimisation measures in the product Risk Management Plan agreed at the time of first authorisation of the product as a Pharmacy medicine or by amending the authorisation of the OTC product. This will give flexibility to companies and MHRA to apply the requirement where appropriate and justified. As a policy this would be in all cases for the minimum period after an ingredient first became available over-the-counter but would also provide flexibility to apply it in other circumstances, for example when an innovative presentation of an existing ingredient first becomes available OTC. The MHRA is also minded to require that training materials for health professionals always contain the full prescribing information.

Question 4 – Do you agree with the proposal to implement the minimum period for extended information through the individual marketing authorisation? If not, what alternative would be satisfactory?

19. The two proposals above aim to simplify the promotion of OTC products for retail sale. Some medicines that are legally classified as GSL and P category may also be promoted for prescription supply. A simple change to the law to permit use of the abbreviated advertisement format for all P and GSL medicines would also permit these

products to use the abbreviated format for advertising to prescribers. The MHRA is minded to seek a legal or self-regulatory solution that will ensure the changes only affect medicines promoted for OTC use so that the advertising requirements in relation to prescription use remain unchanged and are consistent for all products promoted for prescription supply.

Question 5 – Do you consider that the changes set out above to introduce abbreviated advertising formats should also apply to advertisements for P or GSL products that are being promoted for prescription supply? If so, please give your reasons.

C. Authorisation of a link to the full SPC in electronic advertisements as an alternative to the prescribing information.

20. Most SPCs are already made available on the internet and companies have established procedures for keeping them up to date. At present the law requires a summary of this information to be accessible from the advertisement in the form of the prescribing information. For an advertisement in a digital medium (such as on a website), the prescribing information is accessed by a single click. Allowing a single-click link to the full SPC document as an alternative will be of benefit to companies marketing both prescription and OTC medicines. There will be no loss of access to information for healthcare professionals as the whole SPC will be available following a single click in the same way as the prescribing information is currently accessed. The full SPC may be considerably longer than the prescribing information.

Question 6 – Do you agree with the proposal to permit a link to the full SPC in electronic advertisements instead of a link to the prescribing information? If not, please give your reasons.

Other issues

21. We would also like to ask some general questions about the value of the prescribing information included in advertising for prescription medicines. No changes are proposed as part of this consultation but the information gathered will help to inform future consideration of the statutory information requirements in advertising to ensure these are kept up-to-date and relevant to the needs of healthcare professionals.

Question 7 – What do you consider to be the utility of the prescribing information in advertisements for medicines? Do you ever look for information in the prescribing information in advertisements for medicines and why? How does it affect your practice?

22. PAGB also made two further proposals. The first of these relates to the **requirement to include product costs in advertisements** where PAGB argued that this information is readily available to retailers from other sources. The abbreviated advertisement format does not require the inclusion of a price so price will no longer be a requirement for most OTC products advertisements if the above changes are implemented.

23. This information is of utility to prescribers of medicines who manage budgets and views on this are invited. No changes to the requirement for cost information for prescription only medicines are proposed as part of this consultation.

Question 8 – Do you consider that the cost of the product should continue to be included in advertising for medicines to be supplied on prescription?

24. The final PAGB proposal relates to **advertisements for multiple products**. This is already permissible under current law and MHRA and industry guidance will be amended to provide clarity to companies on how to present the prescribing information for multiple products.

Impact Assessment

25. The proposals are intended to reduce the burden on industry to maintain advertising where this can be achieved without compromising access to information required by healthcare professionals and other medicines retailers.

26. **Impact on medicines retailers of proposal A (abbreviated format for advertisements for GSL medicines)**: Industry has argued that there will be no significant costs to pharmacy staff and other medicines retailers from these proposals since the retailers are not required to have medical expertise and the products can be sold without medical supervision.

27. **Impact on pharmacies of proposal B (abbreviated format for advertisements for P medicines after a defined period)**: Industry has argued that there will be no significant costs to pharmacies from these proposals since the proposals relate to older products where pharmacy staff have developed familiarity with the products. We consider that the proposed requirements that initial advertising and ongoing training materials continue to contain the full prescribing information are important.

28. **Impact on healthcare professionals of proposal C (electronic advertisements)**: No cost to healthcare professionals has been identified since full information on the medicine will continue to be available.

Question 9 – Do you agree with these assessments of the cost impact of these proposals on healthcare professionals and medicines retailers? Please provide details of any costs you consider would be incurred.

29. These proposals have the potential to impact on all the approximately 950 pharmaceutical companies holding marketing authorisations and traditional herbal registrations for medicines in the UK and issued by the MHRA or the European Commission. In practice, many companies do not actively market their products to healthcare professionals and other medicines retailers. An initial assessment suggests that there would be overall savings in the order of £960 000 per year based on industry figures. This is calculated as set out below.

30. **Impact on industry of proposals A and B** Estimates from PAGB member companies suggest that the cost of updating a single advertisement when prescribing information changes is in the order of £1000. This is made up of revision and checking by company staff, agency design costs, and printing and distribution charges. If these proposals are implemented, these costs would not be completely removed because the main content of the advertisement would still need to be checked against the new information but the saving would probably be at least £800 for each item.

31. The number of current items of advertising that would need to be updated can vary significantly, depending on the number of products in the brand and how actively it is marketed. Industry examples have given a range from 9 to 56 items to be updated. A conservative assumption of 10 items to be updated is used here, giving an overall cost of £8000 for one revision to all the advertising for one product. Estimates from industry of the number of updates required per product each year were again variable and ranged from 0 to 6.

32. We have conservatively assumed that there only 1 update a year is required for each of the 20 most widely advertised OTC brands. The annual cost saving would therefore be £8000 x 20, £160 000. The move to the new format would most likely be achieved the next time the advertising is updated for other reasons so we have assumed that there would be no additional one-off implementation costs for these proposals.

Question 10 - Do you agree with the estimated savings for proposals A and B? The MHRA would be grateful for any further detail on the estimates provided.

33. **Impact on industry of proposal C**: Preliminary cost estimates quoted by industry for updating digital advertisements were lower than for paper advertisements reflecting reduced printing cost mainly. For updating the prescribing information for one product, these ranged from £4800 to £7200. A figure of £5000 is used for this appraisal.

34. Obtaining an estimate of the number of times each year that a change in the prescribing information in advertising is required because the safety information in the SPC has been updated has proved difficult. A figure of 160 has been chosen for this appraisal. This is based on the numbers of new products and indications authorised through the European centralised licensing system in 2012 (76) and the number of major European safety referrals completed in 2012 (81). These are the products most likely to have updates to their SPC but it is acknowledged that this is only an initial rough and probably low estimate.

35. Based on these figures, the annual cost saving for electronic advertisements would be £5000 x 160, £800 000.

Question 11 - Do you agree with the estimated savings for proposal C? The MHRA would be grateful for any further detail on the estimates provided.

36. We do not believe that the proposals contained in this consultation 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 effect on equality issues under any of the following:

Competition Assessment
Small and Micro Business Assessment
Legal Aid
Sustainable Development
Carbon Assessment
Other Environment
Health Impact Assessment
Race Equality
Disability Equality
Gender Equality
Human Rights
Rural Proofing

Question 12 - Can you think of any costs or effects? Please provide a clear description of who you think would be impacted and in what way.

Circulation of proposals

37. This consultation letter is being brought to the attention of those organisations listed at Annex 2. Copies of the consultation are also available from our website, www.mhra.gov.uk. Replies are welcome from all interested parties.

Comments

38. We welcome views on each of these proposals. You are invited to comment on the proposed changes to legislation set out in this consultation and to provide the information sought on the potential impact of the changes. The full set of questions is reproduced below for ease of reference:

Question 1 – Do you agree with the proposal to permit all GSL product advertising to use an abbreviated format? If not, please give your reasons.

Question 2 – Do you agree with this proposal? If not, please give your reasons.

Question 3 – What is the minimum period an ingredient must have been available OTC for before the abbreviated format of advertisement can be used?

Question 4 – Do you agree with the proposal to implement the minimum period for extended information through the individual marketing authorisation? If not, what alternative would be satisfactory?

Question 5 – Do you consider that the changes set out above to introduce abbreviated advertising formats should also apply to advertisements for P or GSL products that are being promoted for prescription supply? If so, please give your reasons.

Question 6 – Do you agree with the proposal to permit a link to the full SPC in

electronic advertisements instead of a link to the prescribing information? If not, please give your reasons.

Question 7 – What do you consider to be the utility of the prescribing information in advertisements for medicines? Do you ever look for information in it and why? How does it affect your practice?

Question 8 – Do you consider that the cost of the product should continue to be included in advertising for medicines to be supplied on prescription?

Question 9 – Do you agree with these assessments of the cost impact of these proposals on healthcare professionals and medicines retailers? Please provided details of any costs you consider would be incurred.

Question 10 - Do you agree with the estimated savings for proposals A and B? The MHRA would be grateful for any further detail on the estimates provided.

Question 11 - Do you agree with the estimated savings for proposal C? The MHRA would be grateful for any further detail on the estimates provided.

Question 12 - Can you think of any costs or effects? Please provide a clear description of who you think would be impacted and in what way.

How to respond

39. A reply can be e-mailed to: advertising@mhra.gsi.gov.uk or may be addressed to: Abiodun Aderogba, Advertising Standards Unit, Medicines and Healthcare products Regulatory Agency, 3-M, 151 Buckingham Palace Road, London SW1W 9SZ. **Comments must arrive no later than 22 April 2014**. Comments received after this date will not be taken into account. The MHRA will not enter into any correspondence concerning these proposals. Once analysed, a summary of the responses received will be made available on the MHRA website.

40. This consultation abides by the consultation principles published by the Cabinet Office, viewable at:

https://www.gov.uk/government/publications/consultation-principles-guidance

Responses: Confidentiality and Disclaimer

41. 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.

42. 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.

43. **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.**

44. MHRA Customer Services Centre at 151 Buckingham Palace Road will supply copies of responses on request. An administrative charge, to cover the cost of photocopying and postage, may be applied. Alternatively, personal callers can inspect replies at the Customer Services Centre by prior appointment (telephone 020 3080 6351).

Beryl Keeley
MHRA Advertising Standards Unit

Medicines and Healthcare Products Regulatory Agency

REPLY CONFIDENTIALITY FORM: MLX 384

To: Abiodun Aderogba From: _____

MHRA
Room 3-M
151 Buckingham Palace Road
LONDON SW1W 9SZ

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ALL RESPONDENTS MUST TICK ONE OF THE FOLLOWING BOXES

- **My reply may be made freely available** ☐
- **I wish my reply to remain confidential*** ☐
- **I wish parts of my reply to remain confidential*** ☐

*Please use the space below to explain why you feel the information in your reply should be treated as confidential. In line with the Freedom of Information Act 2000, 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. Responses to consultation will not normally be released under FOI until the regulatory process is complete

Explanation regarding why your response should remain confidential

_____

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_____

_____

Name: **Signature**

Date:

CPRD NIBSC MHRA

Annex 1

CURRENT INFORMATION REQUIREMENTS FOR ADVERTISING TO PRESCRIBERS AND SUPPLIERS OF MEDICINES

1. The current information requirements for advertising to prescribers and suppliers of medicines are set out in Part 14 of the Human Medicines Regulations 2012 (SI 2012/1916). Part 14 implements Title VIII of Directive 2001/83/EC.

2. All advertisements for medicines must include the following identifying information:
    a. the name of the product;
    b. a list of active ingredients;
    c. what the product is for (indication for use);
    d. the legal classification (POM, P or GSL), and
    e. the name and address of the supplier.

3. Advertisements must also include 'prescribing information' and the cost of the product. The prescribing information required is a succinct summary of information from the Summary of Product Characteristics (SPC) relating to the use of the product and includes the following:
    a. dosage and method of use;
    b. adverse reactions;
    c. precautions, and
    d. relevant contra-indications.

4. For an 'abbreviated advertisement', the information set out in point 3 above may be substituted by a statement that "Information about this product, including adverse reactions, precautions, contra-indications and method of use can be found at" with a link to a website holding this information or a copy of the SPC for the product.

5. An abbreviated advertisement must be no larger than 420cm^2 and may only appear in a journal or similar publication.

Annex 2

THE ATTENTION OF THE FOLLOWING HAS BEEN DRAWN TO THIS CONSULTATION
Please note that this list is not exhaustive and replies are welcome from all interested parties.

Association of Convenience Stores
Advertising Standards Authority
Advertising Association
ABPI
Association of Independent Multiple Pharmacies
Bioindustry Association
British Association of European Pharmaceutical Distributors
British Association of Homoeopathic Manufacturers
British Association of Pharmaceutical Wholesalers
British International Doctors Association
British Generic Manufacturers Association
British Geriatrics Society
British Herbal Medicine Association
British Medical Association
British Medical Association (Scotland)
British Medical Journal
British Retail Consortium
Chemist & Druggist
Community Pharmacy Northern Ireland
Community Pharmacy Scotland
Company Chemists' Association
Consumers Association
Dispensing Doctors Association
Ethical Medicines Industry Group
Faculty of Homeopathy
General Pharmaceutical Council
General Dental Council
General Medical Council
Health Food Manufacturers' Association
Health & Care Professions Council
Health Which
Herbal Forum
Medical Women's Federation
National Federation of Retail Newsagents
National Pharmacy Association
National Voices
NHS England
NI Centre for Pharmacy Learning and Development (NICPLD)
Nursing & Midwifery Council
OTC Bulletin
Patients Association
Petrol Retailers Association

Proprietary Association of Great Britain
Pharmaceutical Journal
Pharmaceutical Services Negotiating Committee
Pharmaceutical Society of Northern Ireland
Pharmacy in Focus
Pharmacy Magazine
Pulse Magazine
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of General Practitioners (NI)
Royal College of General Practitioners (Scotland)
Royal College of Midwives
Royal College of Midwives (Scotland)
Royal College of Nursing
Royal College of Nursing (N Ireland)
Royal College of Nursing (Scotland)
Royal College of Obstetrics and Gynaecology
Royal College of Ophthalmologists
Royal College of Paediatrics and Child Health
Royal College of Pathologists
Royal College of Physicians & Surgeons (Glasgow)
Royal College of Physicians (Edinburgh)
Royal College of Physicians (London)
Royal College of Psychiatrists
Royal College of Radiologists
Royal College of Surgeons
Royal College of Surgeons (Edinburgh)
Royal Pharmaceutical Society
Royal Pharmaceutical Society (Scotland)
Scottish Health Boards and Special Health Boards
UK Medicines Information
Ulster Chemists' Association