

## DRAFT FOR CONSULTATION

### Homeopathic Medicines: Guidance on advertising

#### 1. Purpose of this Guideline

This guidance has been developed by the Medicines and Healthcare products Regulatory Agency (MHRA) in consultation with the homeopathic medicines sector and advertising regulatory bodies. It is intended for advertisers and suppliers of homeopathic medicinal products.

This guidance interprets the legal requirements for advertising of homeopathic medicines to the public and to homeopathic practitioners and recommends best practice to ensure responsible advertising. It is supplementary to the regulatory framework as set out in the Medicines (Advertising) Regulations 1994 (SI 1994/1932 as amended – the Advertising Regulations), which implement Title VIII of European Directive 2001/83/EC.

Further information and general advice on compliance with the Advertising Regulations is available in the MHRA Blue Guide, *Advertising and Promotion of medicines in the UK*, available on the MHRA website.

On investigation, the decision on whether a particular advertisement complies with the Regulations would be taken by the MHRA on a case by case basis, having regard to the facts of the particular case.

#### 2. Scope of Guidance

All advertising of homeopathic products or services is subject to the general rules on misleading advertising administered by the Advertising Standards Authority. Further information is available at [www.asa.org.uk](http://www.asa.org.uk).

This guidance covers the specific requirements under the medicines legislation for advertising of homeopathic medicines for human use in the UK. Advice is also provided to help ensure that advertising for services which involve the supply of homeopathic products, to practitioners or to the public, does not promote unlicensed homeopathic medicines.

Advertising of medicinal products has a broad definition under the Advertising Regulations and is considered to be anything which is designed to promote the prescription, supply, sale or consumption of medicinal products.

### **3. Regulation of homeopathic products**

There are currently three regulatory schemes for homeopathic products. Under each scheme, products must meet established standards of safety and quality but are not required to demonstrate efficacy.

- Product Licences of Right (PLRs) were issued to all medicinal products on the market at the time that the Medicines Act 1968 was implemented in 1971. Homeopathic products covered by PLRs may include indications.
- The Simplified Registration Scheme was introduced in 1992 under Article 14(1) of European Directive 2001/83/EC. Registered products are not allowed to include indications.
- The National Rules Scheme was introduced in 2006 to regularise the inconsistencies between these two schemes and allows homeopathic products to be indicated for the relief or treatment of mild, self-limiting conditions (those that can ordinarily be relieved or treated without the supervision or intervention of a doctor). The Scheme was implemented by the Medicines for Human Use (National Rules for Homeopathic Products) Regulations 2006 (SI 2006/1952), under article 16(2) of European Directive 2001/83/EC.

All homeopathic products must be either registered or authorised in one of the schemes and companies are encouraged to re-register their existing PLR products in one of the Schemes.

Homeopathic products are licensed for use in minor self-limiting conditions that are suitable for self-management and do not require the intervention of a medical practitioner.

#### **4. Specific requirements for advertising homeopathic medicines to the public**

##### **i. Homeopathic Products with Product Licences of Right**

Advertising of homeopathic products covered by product licences of right will continue to be subject to the provisions of the Medicines (Labelling and Advertising to the Public) Regulations 1978 (SI 1978/41). They are not covered by the Advertising Regulations.

Under these regulations, the following are not acceptable:

- Promotion of a product for any disease listed in the relevant schedules to the regulations unless the specific requirements are complied with.
- Advertising for a product which makes reference to the Advisory Board on the Registration of Homeopathic Products, the Commission on Human Medicines, the MHRA or the Licensing Authority.

##### **ii. Homeopathic Products registered under the Simplified Scheme**

Advertising of homeopathic products registered under the Simplified Scheme is regulated under the Advertising Regulations. Regulation 22 governs advertising of Simplified Scheme homeopathic products. Only the information included on the product labelling registered with the MHRA, listed in Schedule 5 of the Regulations, may be included in advertisements for the product. No mention of a specific indication or therapeutic claims may be made. Advice on permitted labelling is available at:

[http://www.mhra.gov.uk/home/idcplg?IdcService=GET\\_FILE&dDocName=CON007550&RevisionSelectionMethod=Latest&noSaveAs=0&Rendition=WEB](http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON007550&RevisionSelectionMethod=Latest&noSaveAs=0&Rendition=WEB)

Company or product-specific leaflets available at the point of sale are subject to the same restrictions. This does not prohibit the availability at the point of sale of general homeopathic reference materials such as books and independently authored periodicals (e.g. a Materia Medica) describing the uses of a wide range of homeopathic substances.

### **iii. Homeopathic Products authorised under the National Rules Scheme**

Advertising of homeopathic products authorised under the National Rules Scheme is also regulated under the Advertising Regulations. Companies may include the homeopathic use of the product in their advertising. Promotional claims must be consistent with the authorised indication for the product and clearly state that the product is a homeopathic medicinal product used within the UK homeopathic tradition for that indication.

The indication is based upon UK homeopathic practitioners' traditional homeopathic use of the product, and product claims and advertising must be clearly set in the context of traditional use. Advertising that implies that a product's efficacy is based on clinical trial data, or the use of wording to imply that efficacy has been demonstrated, such as 'effective for', or 'works fast to relieve', is not acceptable.

There is an obvious risk of exaggerating the benefits of the product and misleading the consumer if an advertisement presents the results of a clinical trial apparently demonstrating efficacy if information is not clearly set within this context and related to the homeopathic tradition.

**Other requirements for Simplified and National Rules products:** All of the general rules about medicines advertising as set out in the Medicines (Advertising) Regulations 1994 apply to Simplified and National Rules homeopathic medicinal products. For ease of reference, Annex 1 provides a summary list of the other legal restrictions on advertising medicines to the public that apply to these homeopathic medicines. As for all medicines, homeopathic medicinal products should not be described in any advertising or promotional material as "essential" for a general population including people not suffering from any condition.

### **iv. Homeopathic products not registered or authorised by the MHRA**

Advertising of unlicensed medicines in the UK is prohibited. Therefore homeopathic products which do not hold a current registration or authorisation under one of the above schemes must not be advertised.

## v. Remedy kits

Remedy kits advertised for specific indications, e.g. “Childbirth Kit”, may only contain products that are licensed by the MHRA and that have indications (or usage within the homeopathic tradition for Simplified Scheme products) that are relevant to the condition. No product claims may be made for any other kit.

## 5. Advertising homeopathy services

**Homeopathic practitioners** may promote the service they provide for the public, e.g. the availability of a homeopathic consultation service. Details of products in any advertising must be limited to those licensed by the MHRA and must comply with the requirements set out in section 4 above. **[Paragraph amended Nov 11]**

These restrictions apply equally to advertising on the **internet**. Product information, including sales material and any online purchase facility, may only be provided for licensed products.

Any service that offers advice about treatment options based on answers to questions online should ensure that it does not suggest that a medical consultation is unnecessary. Only licensed products may be offered without an individual consultation with a homeopathic practitioner.

For more information, the Borderline Unit has provided specific guidance on how a company can give customers information on websites without making medicinal claims. This is available at:

“The Medicines Borderline Section and the Internet”

[http://www.mhra.gov.uk/home/idcplg?IdcService=GET\\_FILE&dDocName=CON2023338&RevisionSelectionMethod=Latest&noSaveAs=0&Rendition=WEB](http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON2023338&RevisionSelectionMethod=Latest&noSaveAs=0&Rendition=WEB)

**Companies holding a ‘specials’ manufacturing licence** may advertise that they make up individualised remedies to order, e.g. “We can make to order remedies for your patients”. It should be clear that these remedies are not available for supply directly to the public.

This facility may be advertised to authorised health professionals. For products that may legally be supplied without a prescription, the service may also be

advertised to any homeopathic practitioner who intends to supply products as part of a homeopathic consultation in the course of their business.

‘Specials’ manufacturers must not advertise or otherwise solicit orders for specific unlicensed products but they may send out simple price lists to potential health professional customers in response to an enquiry, provided these include no product claims.

**Registered pharmacies** may also advertise that they offer a service to provide individualised remedies to the customer’s specification. In this case the customer does not have to be a health professional.

In each case, details of individualised remedies that may be made up specifically for a patient’s condition should not be provided as this may promote a homeopathic product which is not registered or authorised. For example. “Hayfever Mix” or “An individualised remedy containing XXX and YYY to help relieve stress” would not be acceptable.

All these requirements apply equally to advertising on the **internet**. A factual list of homeopathic ingredients and prices may be provided such as an A-Z list of ingredients and potencies available. The list must not link to any product claims since this is likely to be seen as making claims for and promoting the products. Information and links on the home page should refer to the service being offered and not to products.

Alternatively, a list of generic homeopathic substances and their general use within the homeopathic tradition can be included for general information. Usage information can only be provided if specific unlicensed homeopathic products and product claims are not made and sales information, for example a purchase facility, is not provided on the website. See the advice referred to above on “The Medicines Borderline Section and the Internet” for further guidance.

## 6. Further information and Guidance

Advice on advertising medicinal products is available from the MHRA Advertising Standards Unit at [advertising@mhra.gsi.gov.uk](mailto:advertising@mhra.gsi.gov.uk) and in the Blue Guide, *Advertising and Promotion of medicines in the UK*, on the MHRA website at:

<http://www.mhra.gov.uk/home/groups/pl-a/documents/publication/con2022589.pdf>



General information about homeopathic medicines and the licensing schemes is available on the MHRA website at:

<http://www.mhra.gov.uk/Howweregulate/Medicines/Homeopathicmedicines/index.htm>

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## **Annex 1**

This annex briefly summarises the general requirements under the legislation on advertising to the public for homeopathic medicines authorised under the National Rules and Simplified Schemes.

### **A. Statutory requirements for advertising to the public**

All advertising to the public of homeopathic medicines authorised under the National Rules Scheme must include:

- the name of the product or a reasonable abbreviation thereof,
- the scientific name(s) of the stocks,
- at least one indication for use consistent with the terms in the SPC,
- a clear and legible invitation to “Always read the label” or leaflet,

The only exception is for promotional aids which may only contain the brand name of the product, trademark or the scientific name(s) of the stocks.

For homeopathic medicines under the Simplified Scheme the information that may be contained in advertising is limited to the items permitted for inclusion on the labelling of the product. No other information may be included.

### **B. Summary of other key statutory requirements**

A homeopathic medicinal product must not be promoted before a registration/marketing authorisation is granted.

All advertising must:

- comply with the particulars listed in the summary of product characteristics (SPC);
- encourage the rational use of the product by presenting it objectively and without exaggerating its properties;
- not be misleading.

All promotional material must be clearly identified as an advertisement.

Manufacturers and suppliers must not provide free sample(s) of a homeopathic product to any member of the public.

### **C. What advertising must not include**

Regulation 9 provides that advertising to the public must not:

- give the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by post, FAX or telephone;
- suggest that the effects of taking the medicinal product are guaranteed, are unaccompanied by side effects or are better than, or equivalent to, those of another identifiable treatment or medicinal product;
- suggest that health can be enhanced by taking the medicinal product;
- suggest that health could be affected by not taking the medicinal product;
- be directed exclusively or principally at children;
- refer to a recommendation by scientists, health professionals or persons who because of their celebrity, could encourage the consumption of medicinal products;
- suggest that the medicinal product is a foodstuff, cosmetic or other consumer product;
- suggest that the safety or efficacy of the product is due to the fact that it is natural;
- be such that it might, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- refer, in improper, alarming or misleading terms, to claims of recovery;
- use, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts of it.

### **D. Further information**

For further information, consult the Blue Guide, *Advertising and Promotion of medicines* available on the MHRA website at:

<http://www.mhra.gov.uk/home/groups/pl-a/documents/publication/con2022589.pdf>