

DRAFT FOR CONSULTATION

Registered Traditional Herbal Medicines: Guidance on Consumer Advertising

1. Purpose of this Guideline

This guidance has been developed by the Medicines and Healthcare products Regulatory Agency (MHRA) in consultation with the herbal medicines sector and advertising regulatory bodies.

The guidance is supplementary to the regulatory framework as set out in the Medicines (Advertising) Regulations 1994 (SI 1994/1932 as amended), which implement Title VIII of European Directive 2001/83/EC.

The guidance is intended for advertisers of traditional herbal medicinal products (THMs) holding a registration certificate granted by the MHRA under the Traditional Herbal Medicines Registration Scheme. This is the Scheme that implements the requirements of the Traditional Herbal Medicines Directive (Directive 2004/24/EC).

Products registered under this Scheme must meet established standards of safety and quality for medicines but, instead of the recognised efficacy standards required for a marketing authorisation, the product must have been used for at least 30 years (at least 15 of which must normally have been within the EU) to demonstrate long-standing traditional use in the specified conditions of use.

This guidance interprets the legal requirements for advertising to the public and recommends best practice for advertisers to ensure safe and responsible advertising of these medicines. It reflects the general principles to be adopted so that advertising does not convey misleading messages that could lead to inappropriate use of these medicinal products.

Further information and general advice on compliance with the medicines advertising legislation 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 law 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

This guidance covers all consumer advertising for registered traditional herbal medicines in the UK.

Although some of the requirements and restrictions may also apply to advertising aimed at healthcare professionals, this guidance does not cover advertising directed at healthcare professionals. Requirements are set out in the MHRA Blue Guide.

3. General Statement

It is a central feature of the traditional herbal medicine registration scheme that the products concerned do not fulfil the requirement to demonstrate efficacy for a marketing authorisation. In particular, such products will not fulfil the efficacy requirements for a well-established medicinal use. If a product fulfils the criteria for a marketing authorisation, then it is not usually appropriate to grant that product a traditional herbal registration.

THMs are generally registered for use in minor self-limiting conditions that are suitable for self-management and do not require the intervention of a medical practitioner.

All of the general rules about medicines advertising as implemented by the Medicines (Advertising) Regulations 1994 apply to traditional herbal medicinal products. There is one additional requirement for advertising of these products, to include a specified form of wording to inform the consumer that the efficacy of the product for the stated indications is not scientifically supported but is based exclusively on evidence of long-standing use.

4. Specific requirements for advertising THMs to the public

4.1 THM statement

All advertising for THMs, to the public or to health professionals, must include the statement:

“Traditional herbal medicinal product for use in [*specify one or more indications for the product consistent with the terms of the registration*] exclusively based upon long-standing use as a traditional remedy”.

The words “as a traditional remedy” have been added to the statement required by law to ensure that consumers are not misled as to the length of time they need to take the product.

The exact wording above must be used (with the italic section completed with appropriate indication(s) for use of the product).

If placed clearly in the body of the advertisement rather than as a footnote, this text meets the requirement to include an indication for use of the product in advertising to the public.

4.2 Indication statement

Advertisements must include at least one indication for use of the product.

THMs are generally registered with an indication such as “A traditional herbal medicinal product used for the temporary relief of symptoms of [*a specific condition*] based on traditional use only”. All advertising must reflect the approved indication accurately and in its entirety. Text does not need to use the exact wording in the Summary of Product Characteristics (SPC) but the meaning should be clear. As an example for the indication above, it should be clear that that the product is:

- a traditional remedy/traditionally used or similar wording
- for relief of symptoms (i.e. not for curing the condition)
- for short term (temporary) use
- for treatment of the specified condition
- where the condition includes a reference to its severity, e.g. mild or moderate, this should be included. Words or illustrations should not suggest that a more serious degree of the condition can be treated.

For maximum clarity it is recommended that the full indication is included prominently in one place in the body of the advertisement.

4.3 Making other claims for the product

Additional claims must be clearly set in the context that the indications for the product are based exclusively on longstanding use.

As an example, wordings such as “traditionally used as a remedy/treatment for ...” or “XXX has been marketed for many years as a traditional remedy for ...” would be likely to be acceptable.

Wordings that imply efficacy has been demonstrated such as “clinically proven”, “effective for ...” or “works fast to relieve ...” are unlikely to be acceptable.

References to clinical studies

The required THM statement is clearly intended to inform the consumer that the efficacy of the product for the stated indications is based exclusively on long-standing use, i.e. that there were insufficient clinical data to demonstrate the efficacy of the product. There is therefore an obvious risk of exaggerating the benefits of the product and misleading the consumer if the advertisement then goes on to explain the results of a clinical trial apparently demonstrating efficacy.

In order to ensure that consumers are not misled when presenting the results of limited clinical studies, it is important to make clear the basis on which the product was registered, i.e. that there were insufficient clinical data to demonstrate the efficacy of the product. In practice, given the nature of the traditional herbal scheme, it would be particularly difficult, in brief advertisements, to make reference to clinical trial data without misleading consumers. In principle it may be more feasible that compliance with the regulatory requirements may be achievable in a longer, more narrative type of advertisement (‘advertorial’), but the practicalities of this would need careful consideration.

There are also specific problems with including clinical evidence. It would be misleading for an advertisement to selectively refer to the results of particular studies which showed the efficacy of the product in a particular light, when there were also other less favourable studies available that cast doubt on the efficacy of that product. A further issue is that, historically, there will have been numerous clinical studies of various herbal ingredients, but MHRA experience suggests that many of them are likely to have had flaws, sometimes fundamental ones, in design and/or control, which seriously limit their value in providing information useful to the consumer.

Testimonials

These may be used in advertising but any statements must be in line with the indication for traditional use and must not suggest that the product has proven efficacy. Similar concerns arise as for references to clinical studies above and it would not be possible to include testimonials that make personal efficacy claims for a THM product in brief advertisements because of the potential to mislead. In a more detailed piece such as a website, MHRA takes the view that it may be possible to include a genuine factual testimonial based on personal use. Any testimonial must be clearly set in the context that the product is a traditional remedy and it must be explicitly stated that this represents one person's experience and the efficacy of the product has not been proven.

4.4 Other requirements

For ease of reference, Annex 1 provides a summary list of the other legal restrictions on advertising medicines to the public that apply to all OTC medicines, including registered THMs.

4.5 Voluntary THM identifier

The MHRA is in the process of registering an identification mark that companies may, if they wish, include in their advertising and/or on pack labelling to help the public to identify that the product holds a THM registration. Details are available from *[complete when available]*.

5. Self regulation in the UK

A system of self regulation for medicines advertising has been long established in the UK. This includes Codes of Practice and advice and vetting services for consumer advertising prior to publication. For over the counter medicines and THMs, these services are provided by the following organisations:

British Herbal Medicine Association	www.bhma.info
Health Food Manufacturers' Association	www.hfma.co.uk
Proprietary Association of Great Britain	www.pagb.co.uk

As a condition of membership, these organisations require their members to submit all advertising to the public for vetting prior to issue. The MHRA supports self regulation as it sets high standards and promotes good practice. Its effectiveness is demonstrated by the very low numbers of complaints about advertising to the public received by the MHRA. The MHRA encourages all advertisers of traditional herbal medicines to join one of these associations to provide external assurance that proposed advertising to the public complies with the legislation. Where complaints are upheld about advertising, the MHRA will consider the need to require vetting of future materials to ensure compliance if this is not already provided for through self regulation.

Advertisements for medicines must also comply with the general controls on advertising operated by the Advertising Standards Authority. Further information is available at www.asa.org.uk.

6. Further information & Guidance

Further information and general advice on compliance with the advertising legislation is available from the self regulatory bodies listed above and in their Codes of Practice.

Advice is also available from the MHRA Advertising Standards Unit at 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 herbal medicines and the THM Registration Scheme is available on the MHRA website at:

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

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Annex 1

This Annex briefly summarises the general requirements under the legislation on advertising THMs to the public.

A. Statutory requirements for advertising to the public

All advertising of THMs to the public must include:

- the name of the product or a reasonable abbreviation thereof,
- the common name of the product, if the product contains only one active ingredient,
- 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 statement “Traditional herbal medicinal product for use in [*specify one or more indications for the product consistent with the terms of the registration*] exclusively based upon long-standing use as a traditional remedy”.

The only exceptions are for promotional aids (eg pens) which may only contain the brand name of the product, trademark or its international non-proprietary name and factual announcements which include no product claims.

B. Summary of other key statutory requirements

All advertising must:

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

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

A THM product must not be promoted before a registration is granted.

All promotional material must be clearly identified as an advertisement.

C. What advertising must not include

Regulation 9 of the Medicines (Advertising) Regulations 1994 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;
- 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.