

Advertising of medicines: Guidance for providers offering medicinal treatment services

1. Purpose

This guidance has been developed by the Medicines and Healthcare products Regulatory Agency (MHRA) and is supplementary to the regulatory framework as set out in Part 14 of the Human Medicines Regulations 2012 (SI 2012/1916 as amended – the Regulations) which implement Title VIII of European Directive 2001/83/EC. General advice on compliance with the Regulations is given in the MHRA Blue Guide.

The internet is used widely to provide information to consumers and to promote products and services. This guidance is intended primarily for companies and organisations which do not hold marketing authorisations for medicines but which provide services that may lead to the prescription and supply of a prescription only medicine (POM). The guidance seeks to ensure that the content of websites and other digital communications channels does not contravene the Regulations. In particular, it highlights the prohibition by regulation 284 of the Regulations of advertisements to the public likely to lead to the use of a POM. It is designed to help advertisers to promote their services without promoting specific POM medicines and thereby coming within the scope of the Regulations.

If a complaint is received, the decision on whether a particular communication complies with the Regulations will be taken by the MHRA on a case by case basis, having regard to the circumstances of the particular case.

2. Scope of guidance

All advertising of medicinal products or related services is subject to the general rules on misleading advertising administered by the Advertising Standards Authority (ASA). Further information is available at www.asa.org.uk.

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

This guidance covers all websites for consumers, registered in the UK or aimed at the UK audience, which provide services that may lead to the prescription and supply of a POM. Such sites must not promote POMs to the public as this is in breach of UK medicines advertising legislation. It also provides guidance on how to avoid promoting POMs in social media.

The guidance does not cover materials directed at healthcare professionals.

3. General principles

Services such as online clinics, cosmetic treatment providers or pharmacies may promote the service they provide (e.g. medical consultation for individuals with erectile dysfunction or treatments for lines and wrinkles). They may make information available on a certain condition and its management, which may include a balanced overview of the range of therapeutic options. Such material should not draw attention to specific prescription only medicines (POMs) since this is likely to breach the Regulations by encouraging individuals to request a particular treatment and this may result in the prescription and use of a POM. The appropriate management for a condition in an individual patient is for the prescriber and patient jointly to consider and this may include a number of medical factors as well as a range of therapeutic options. Prescribers have a responsibility to provide information about the products they prescribe.

4. Guidance on ensuring website content does not promote medicines

Information on a particular condition or disease may be provided on websites. Care must be taken when providing information relating to POMs. This should be presented in the context of a balanced overview of all treatment options and relevant disease information. Further specific advice is available in the MHRA Disease Awareness Guidelines in Appendix 7 of the Blue Guide.

The Home page should focus on medical conditions and the service the website provides and should not include any reference to named POMs, including price information (see below). Links and navigation aids may be given for particular conditions and diseases but not to specific POMs. Hover text and any small print at the bottom of the home page should also not refer to specific POMs. This provision is designed to ensure that casual browsers are not presented with advertising for specific POMs.

Further pages about the condition, which the consumer chooses to access, may contain **non-promotional** information on specific medicines provided this is presented in the context of a fair overview of the treatment options. (See the section on product claims below for more information.)

It should be clear that the customer is being offered a medical consultation and that this may or may not lead to the provision of a prescription.

Prices

On the homepage, only indicative prices for a particular medical condition may be provided, for example, "Erectile dysfunction treatment - £20 for a medical consultation, £50 for an initial course of 4 treatments." Any mention of prescription only medicines on the home page is likely to be considered as advertising of prescription only medicines to the public. A factual list of prices for available treatments and/or pack sizes may be provided on pages other than

the home page. The price list should not include product claims or actively encourage viewers to choose a product based on the price.

Special offers on prices of medicines should not be highlighted on the website as they are likely to promote the specific prescription only medicine.

The information associated with price lists should make it clear that the viewer's preferred option will not be prescribed if it is not suitable. Decisions about treatment are for the prescriber and patient to jointly consider during consultation and are not based solely on the price.

Icons

It is permissible to use icons to encourage people to undertake a medical consultation. Icons or other features encouraging the purchase of POMs for example, "Buy Now", "Buy XXX", "Add to Basket", etc. should not be used on websites offering POM treatments. These invite consumers to purchase POMs and are intended to promote sales.

Product claims

Specific POMs should not be promoted as this is likely to encourage the purchase of a POM and contravene the Regulations. All information about medicines should be balanced and factual, for example "XXX is used to treat ..." rather than "XXX, the best/fastest/strongest/etc. treatment for ...". Suitable sources of evidence to support non-promotional material are the patient information leaflet or summary of product characteristics for the product, often available on the UK website of the company marketing the product.

Unlicensed medicines should not be mentioned, to comply with regulation 279 of the Regulations which prohibits advertising of medicines for which no marketing authorisation or registration is in force.

Competitive Tools (Meta-tags/ Meta-descriptions/ Meta-Keywords)

Our main focus is the content of the website, rather than the competitive tools used to increase awareness of the website which are not usually prominent in customer views.

Website addresses

Website addresses should not name specific POMs in their core URL (e.g. www.wesellXXX.co.uk). Website addresses like this may be considered to promote a POM to the public.

Sponsored links

The text may promote the service provided but should not mention specific prescription only medicines.

5. Websites offering prescription dispensing services

Where a website dispensing service is aimed specifically at patients who already have a prescription, provided no product claims are made beyond a

simple disease category, the MHRA would not object to a list of products and dispensing prices.

Where a dispensing service is promoted in association with an online consultation service, the restrictions in section 4 above will apply.

6. Guidance on social media

The prohibition on advertising of prescription only medicines to the public applies to social networks such as facebook and twitter in the same way as for traditional media such as magazine advertisements or displays on clinic premises. Any mention of the availability of a named prescription only medicine from a clinic in social media is likely to be considered to be an advertisement which is prohibited.

Prescription medicines should not be named in posts that are linked to the services being provided. This does not prevent factual comment on topical news items in social media but this should not be used to promote prescription only medicines (POMs) to the public.

Any claims relating to prescription only medicines made by service providers in tweets or other social media may encourage consumers to seek treatment with the medicine from that particular provider and the material would be likely to be considered to be an advertisement for a medicine which is prohibited.

7. Enforcement priorities

Our enforcement approach for web-based treatment services takes the potential risk to public health into account. We focus primarily on material on the home pages of clinic websites. The aim is to ensure that customers who are seeking general information on the internet about a clinic or potential treatments are not presented with material promoting POMs. This is similar to our approach for other forms of advertising for services, e.g. in magazines, where mention of POMs is not permitted.

To target our resources, we have chosen not to focus on information that is found by the browser who chooses to access information about specific treatment options for their condition on a clinic website. The MHRA will not routinely review material on website pages other than the home page where this is clearly set in the context of a balanced overview of treatment options. Action will only be taken if a complaint is received that the presentation of information is overtly promotional and not set in the context of a consultation or we consider that misleading information poses a risk to public health. Details of the approach taken by the ASA are provided below.

The MHRA takes robust enforcement action where a significant risk to public health has been identified from advertising to the public for unlicensed or prescription only medicines.

Failure to comply with the Regulations will result in the Advertising Standards Unit requesting that the website is amended or withdrawn. Cases may also be referred to the Inspection, Enforcement and Standards Division for consideration of legal action or other measures leading to the removal of the website or merchant trader account.

In areas where the ASA has established precedents, we may refer complaints to them. Clinics and individual healthcare professionals may also be referred to their professional regulators if compliance is not achieved in a timely fashion.

8. Further information

Further information and advice is available from the MHRA Advertising Standards Unit at advertising@mhra.gsi.gov.uk and in the Blue Guide⁵, *Advertising and Promotion of medicines in the UK*, available on the MHRA website.

The Advertising Standards Authority (ASA) has a general remit to ensure that advertising, complies with the UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing. ASA may take action on any aspect of a company's marketing that does not comply with the Code, including material found on any part of a company's website. Details of their work are available at www.asa.org.uk

Registered pharmacies are also encouraged to display the Internet Pharmacy logo of the General Pharmaceutical Council (GPhC) on their website home page to assure consumers that medicines are supplied by a registered pharmacy. Details of this scheme and how to join are available on the GPhC website at:

<http://www.pharmacyregulation.org/regulatingpharmacy/registration/internetpharmacy/index.aspx>.

The websites of pharmaceutical companies are covered by self regulatory codes of practice operated by the Prescription Medicines Code of Practice Authority⁶ and the Proprietary Association of Great Britain⁷.

Clinics may also be regulated by the Care Quality Commission (www.cqc.org.uk) and individual prescribers by their own professional body (e.g. the General Medical Council for doctors).

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⁵ The MHRA Blue Guide, *Advertising and Promotion of Medicines in the UK*, is available on the MHRA website at www.mhra.gov.uk.

⁶ The ABPI Code of Practice for the Pharmaceutical Industry covers prescription medicines and is available on the PMCPA website at www.pmcpa.org.uk.

⁷ The PAGB Medicines Advertising Codes cover over-the-counter medicines and a summary is available on the PAGB website at www.pagb.org.uk.