

Disease Awareness Campaign Guidelines

Introduction

1. There is general agreement on the importance of providing high quality information to patients and the public about health and disease. This guideline addresses the content of Disease Awareness Campaigns (DACs).
2. DACs are concerned with providing information, promoting awareness or educating the public about health, diseases and their management. DACs must not promote medicinal products to the public. The advertising of medicinal products is regulated by Title VIII of European Directive 2001/83/EC and the UK implementing legislation; Part 14 of the Human Medicines Regulations 2012 (S.I. 2012/1916 as amended – the Regulations). A key provision of this legislation is the prohibition of advertising of prescription only medicines direct to the public. Campaigns that include no direct or indirect references to medicinal products fall outside the scope of Title VIII of Directive 2001/83/EC.
3. DACs are an increasing feature of medical information in the UK. They can provide a valuable source of information to the public on diseases and conditions, aid recognition of symptoms and highlight appropriate sources of advice. This guideline sets out principles on how to ensure that DACs remain informative without constituting advertisements that fall within the scope of Title VIII of Directive 2001/83/EC and provides additional advice to promote good practice. Evidence-based general guidance on how to write health and disease related leaflets in terms that recipients can understand and identify with is available from other sources and this guideline is intended to supplement, but not replace, this.

General principles

4. The primary purpose of a DAC must be to increase awareness of a disease or diseases and to provide health educational information on that disease and its management. It should not promote the use of a particular medicinal product or products. Campaigns which aim to stimulate demand by the public for a specific medicine or specific medicines, are likely to be considered promotional, falling within the scope of Title VIII of Directive 2001/83/EC.
5. A DAC may make reference to the availability of treatment options (which may include medicines as part of a range of possible management options) but this should not be of such a nature that an individual would be encouraged to approach a prescriber to request a particular medicinal option. The emphasis of the material should be on the condition and its recognition rather than on the treatment options.

The appropriate treatment for each disease is for the healthcare professional to decide in consultation with the patient.

6. DACs for diseases or conditions where there is only one, one leading or few medicinal treatments potentially draw attention to one medicinal product, albeit indirectly, regardless of whether it is referred to or not. DACs in these circumstances require particular care. It is particularly important that these campaigns focus on health and disease education, with details of where to get appropriate advice.
7. DACs should include information that is:

Accurate: The information in a DAC should be carefully checked for accuracy so that the public is not misled.

Up-to-date: Every effort should be made to ensure that information contained in a DAC is current. The date of publication should be clear.

Substantiable: The information in a DAC should be capable of substantiation by reference to the medical literature or other authoritative sources.

Comprehensive: DACs should cover the key characteristics of the disease.

Balanced and fair: DACs should ensure that the impact/implications of the disease are realistically conveyed without being alarmist. Management options should be presented in a balanced and fair manner that does not unduly emphasise particular options or the need to seek treatment.

Readable/accessible: The language used should be designed to convey key messages clearly, supported by appropriate design and formatting.

Source identified: The source(s) of the DAC should be clearly identified on the publication itself.

Structure

8. The most appropriate structure for presenting the information will vary depending on the disease or condition and the medium used. The advice below is not intended to restrict or prescribe the format and content of DACs beyond the legislative requirements but the inclusion of

information on the areas outlined below will help to ensure that campaigns communicate appropriate health messages to consumers.

Identification of symptoms or risk factors

An important aspect of any health promotion campaign is to raise awareness of the symptoms or risk factors associated with the disease so that members of the public can seek early diagnosis and treatment, minimise disease progression or avoid complications. The information provided should help the public to be able to recognise the disease, or risk factors for it, in themselves or others and take preventive measures, if appropriate.

General information about the disease

The DAC should provide general background information on the disease including aetiology where appropriate.

Advice for the patient

DACs should point out what the patient needs to do immediately, if necessary, and where to get appropriate advice on management options. Depending on the disease concerned, it may be appropriate to explain the benefit of e.g. lifestyle changes, etc. Nevertheless, the main objective for DACs is to encourage people to take appropriate steps, which may include seeking advice from appropriate healthcare professionals.

Further information

DACs can include sources for additional advice such as helplines and relevant charities and patient groups. If patients are asked to write in for further information, their personal details should only be used for educational purposes connected with the initial enquiry.

Further information

9. The Medicines and Healthcare products Regulatory Agency will offer advice on whether proposed DACs fall outside the scope of Title VIII of Directive 2001/83/EC or not. The MHRA also undertakes routine monitoring of advertisements and investigates any complaints received about them. Guidance on the legislative framework governing advertising control is available in the MHRA Blue Guide, *Advertising and Promotion of Medicines in the UK*, available from the MHRA website at <http://www.mhra.gov.uk/home/groups/pl-a/documents/publication/con2022589.pdf> or from the Stationery Office.

MHRA
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