





COMMENTARY

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Recommendations for the ethical conduct of vaccination awareness campaigns by biopharmaceutical companies

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ABSTRACT

Health awareness campaigns educate and inform the public about particular health conditions with the aim of either changing behavior or enhancing uptake of appropriate healthcare, such as vaccination or screening. The campaigns may be run by governments and public health bodies but are also deployed by biopharmaceutical companies. Industry-sponsored disease awareness (DA) campaigns intend to provide information about diseases and their prevention or treatment, without mentioning specific products. In most countries, DA campaigns fall outside of the laws and regulations that apply to promotion of medicines. Currently, guidance for industry is limited and only exists at national level. This article provides an overview of existing guidance on DA campaigns, discusses benefits and risks, and proposes recommendations for industry-sponsored vaccination awareness campaigns.

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Introduction

Disease awareness (DA) campaigns are designed for the benefit of the general public or patients who have an identified health information need. These campaigns commonly use posters, and media channels such as television, magazines or newspapers, websites, and social media. They provide information about a health-related condition and how to recognize, prevent or treat it. The aim is to trigger a change in behavior with a view to improving public health. Governments or public health institutions sponsor campaigns to enhance health by addressing risky behaviors, such as tobacco smoking, or to encourage the uptake of healthcare, such as cancer screening. Increasingly, DA campaigns are also sponsored by biopharmaceutical companies for diseases for which the company has specific expertise, as, for example, in vaccinology, and hence can contribute to public health.

Currently, there is no regulatory framework or harmonized guidance to ensure ethical conduct of DA campaigns related to vaccine-preventable diseases. Nevertheless, as shown during recent disease outbreaks and epidemics, there are significant knowledge gaps and even misinformation on vaccines and vaccination, leading to low vaccine confidence driven by a mix of psychological, sociocultural, and political factors.^{1,2} In the particular context of the global COVID-19 pandemic, vaccine rejection has been most strongly correlated with public distrust of vaccine benefit, and also correlated with concerns about commercial interests from pharmaceutical companies and preferences for natural immunity.³

In this paper, we focus on vaccination awareness campaigns (VACs), i.e., DA campaigns related to vaccine-preventable diseases, sponsored by biopharmaceutical companies and directed toward the general public. We begin with an overview of existing regulatory frameworks and guidelines. This is

followed by a general discussion of the benefits and risks of VACs. Next, we propose practical considerations to guide ethical conduct of VACs based on our experience at GSK. Finally, we invite companies to share their experiences with a view to strengthening the public health impact of industry sponsored DA campaigns. Disease information directed at healthcare providers (HCPs), specialists or patient representatives; press releases from companies; promotional product campaigns or linked disease awareness and promotional product information are all out of scope of the current paper since they represent specific and distinct ethics issues.

Regulatory framework and guidelines

DA campaigns are distinct in tone and intent from promotional campaigns that are focused on selling specific products. As such they fall outside of regulations on promotion. Promotion of medicines directed to the general public, known as direct-to-consumer advertising (DTCA) of prescription medicines, is only allowed in New Zealand and the US. In common with all the other countries, Europe prohibits the advertising of prescription-only medicines to the general public. European Directive 2001/83/EC does, however, permit the supply of information to the public on health and diseases, provided there is no direct or indirect reference to a pharmaceutical product.⁴ The Directive makes particular reference to vaccination campaigns carried out by the industry: where these are approved by the competent authorities of the Member States, the prohibition of promotion of prescription medicines is not applicable. Canadian authorities, in contrast, permit reminder advertisements which mention the product name but not the indication, as well as 'help-seeking announcements' which present only the medical disorder, but do not refer to a drug product or manufacturer.^{5,6}

DA campaigns are not subject to specific requirements of the US Federal Food, Drug and Cosmetic Act, US Food and Drug Administration (FDA) regulations, or of EU Directive 2001/83/EC. Neither do the FDA or the European Medicines Agency (EMA) provide any specific guidance on the topic. They are also out of scope of international and regional industry associations' codes of practices – their focus is on interactions with HCPs, medical institutions and patient organizations, not the general public. Other regulations such as the General Data Protection Regulation (GDPR) in Europe and national legislations apply only to specific aspects, for example, protection of data privacy regarding the use of pictures of patients in the DA materials.

The few examples of published national guidelines for DA campaigns can be found in an FDA guidance from 2004 (subsequently withdrawn and not later reissued), UK Medicines and Healthcare products Regulatory Agency (MHRA) Blue Guide, Health Canada Policy on Distinction between advertising and other activities with the example of 'Help-seeking announcements,' the Australian Pharmaceutical Industry (Medicines Australia) Code of Conduct, and Israel's guidance.^{7–12} **Table 1** summarizes the key principles from these documents for DA campaigns.

Additionally, although it does not cover DA campaigns, the Dutch Code of Conduct (CoC) for pharmaceutical advertising¹³ includes a specific set of requirements relating to information on pharmaceutical products that are equally relevant to the development and use of DA materials. The Association of the British Pharmaceutical Industry (ABPI) Code of Practice does mention DA campaigns and refers to the MHRA Blue Guide for more detailed guidance.¹⁴

Benefits and risks

The number of DA campaigns has grown rapidly in the US,¹⁵ as well as in countries where DTCA is forbidden.^{16–18} DA campaigns are part of companies' strategies to encourage patients to seek help for medical conditions for which prescription drugs are available.⁵ There is evidence that patient requests for medication subsequent to DA campaigns may influence doctors' prescription behavior and this raises concerns that warrant ethical recommendations.¹⁹

Arguments made in favor of DA campaigns include the promotion of patient autonomy and improved public health thanks to increased diagnosis, better management and treatment of rare, serious or debilitating diseases, as well as destigmatization of diseases (e.g., HIV) or embarrassing symptoms (e.g., erectile dysfunction).^{15,16,20–22} The Israeli Ministry of Health established regulations regarding DA campaigns to specifically empower consumers by providing them with information about the availability of treatments for diseases (medications or preventive treatments) in a manner that does not involve the promotion of a particular commercial product.²¹

Criticism of DA campaigns points at overdiagnosis as a result of so-called disease mongering, a term originally referring to the medicalization of ordinary life, used by Moynihan and colleagues as “*extending the boundaries of treatable illness to expand markets for new products.*”²³ This practice has been linked to the medicalization of normal health and aging, and consequently the risks linked to overtreatment.^{5,15,22–24} In the

case of DA campaigns for vaccine-preventable diseases, concerns over disease mongering are not considered directly relevant since they may entail a risk of overstating disease seriousness and its consequences but not overdiagnosis *per se*.

Recommendations for vaccination awareness campaigns

The primary aim of DA campaigns is to benefit the public, patients, and population health in general by informing and increasing knowledge of how to prevent or treat diseases.

DA campaigns have the potential for mutual benefit, both to the sponsor and the target audience. If successful, the outcome should be an improvement in the corresponding aspect of public health, such as disease cases prevented. For government, savings in healthcare-associated costs may also be achieved. In the case of industry-sponsored campaigns, an ethical tension exists in that a successful DA campaign is likely to increase prescribing by healthcare professionals¹⁶ and runs a risk of being perceived as disguised promotion.

We discuss key parameters relevant to the ethical conduct of vaccination awareness campaigns and systematically formulate corresponding best practice recommendations, which are then subsequently summarized in **Box 1**.

Clarity of intent

An ethically sound DA campaign starts with the right intent. Guidelines published to date describe their purpose as the provision of medical health information and promotion of education for patient health (**Table 1**). This is aligned with the public's assumed benefits of DA campaign, which include heightened awareness of disease and treatment options, as well as creating opportunities for valuable discussions with doctors. Nevertheless, one study reported a majority of respondents also supposed that the intent of DA campaign is to sell more medicines.¹⁸ Thus, the intent should be substantiated by evidence of the target audience's need to be informed from the outset of campaign design. This need or knowledge gap can be identified through surveys or literature review, with the aim to establish precisely what information should be supplied to address this need and result in a health benefit for the public. There should be evaluation of the effectiveness of campaign materials and messages before launch, as well as a plan for ongoing evaluation post-launch, which includes the possibility to adapt if there are misunderstandings or concerns from the public.

In addition, DA campaigns for the general public should not be run at the same time as promotional activities for HCPs in the same disease area, as this may create confusion regarding the original intent of the DA campaign.²⁵

Recommendations

- Identify target audience's needs.
- Address those needs by providing disease information relevant for the target audience.
- Assess the public's response and correct understanding of the message, adapting if appropriate.
- Do not run concurrent branded promotional campaigns for HCPs in the same disease area.

Table 1. Guidance for disease awareness campaigns.

Topic	UK MHRA: DA ⁸	Health Canada Policy: Help-seeking announcements including 1–800 numbers ⁹	US FDA: Guidance for Industry 2004 (Withdrawn) ⁷	Australian Pharmaceutical Industry (Medicines Australia): Code of Conduct- Edition 19 and CoC Guidelines (2016) ¹⁰	Israel's DA Guidance (#134) ^{11,12}
	Focus on disease instead of specific treatment options.		Disease or health condition specific.	Medical conditions and prescription treatments/ focus on conditions instead of treatment options.	
Audience	General public	General public.	Population at risk of or affected by disease or health condition.	General public.	Should be directed at adult members of the general public only.
Intent	Increase awareness of disease(s) and provide medical health information on disease and its management. Aid to recognize symptoms. Highlight appropriate source(s) of advice.		Enhance education.	Educational and should encourage patients to seek further information from HCPs.	Promoting education for patient health.
Responsible public health message	Structure of the information to be included: - symptoms or risk factors - general information on the disease - advice for the patient (refer to HCP).	For 1–800 numbers: The content is disease related rather than product related. The various treatment options (drug and nondrug) and their respective risks and benefits are discussed in an objective manner.	Information on prevention, diagnosis or treatment of a disease or condition.	DA must reflect severity and prevalence of disease in the community (not more serious/prevalent) and be consistent with current body of evidence.	Discuss disease states, their mechanism of action and impact on the human being, their diagnosis and shall not contain any reference to potential treatments.
Seek help	Patient advice and further information.		Refer consumers to qualified HCP for information.	Should be clearly stated that appropriate treatment is for HCP to decide, in consultation with the patient.	Promote with treating physician.
Style	Accurate, up to date, substantiable, comprehensive, balanced and fair, readable/accessible.		Clear and accurate. Avoid encouraging self-diagnosis and self-treatment.	Tone should not unnecessarily cause alarm or misunderstanding nor stimulate demand for prescription of a particular product. Information should be presented in a comprehensive, balanced and fair manner, with no emphasis on particular options or need to seek treatment.	Accurate, up to date, scientifically based, fair, accessible and referenced. The language of the campaign should not include frightening tactics in order to convince the public.

(Continued)

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	UK MHRA: DA ⁸	Health Canada Policy: Help-seeking announcements including 1–800 numbers ⁹	US FDA: Guidance for Industry 2004 (Withdrawn) ⁷	Australian Pharmaceutical Industry (Medicines Australia): Code of Conduct- Edition 19 and CoC Guidelines (2016) ¹⁰	Israel's DA Guidance (#134) ^{11,12}
Product and Branding	May make reference to available treatment options but should not encourage to approach prescriber to request a particular medicinal option. Do not use brand names.	Help-seeking announcements: No specific drug is identified. There is no implication that a drug is the sole treatment available for the disease or condition. 1–800 numbers: No emphasis is placed on one drug product, e.g., excessive use of a brand name or description as a 'breakthrough,' and no emphasis is accorded to the merits of one drug product. No reference is made to an unauthorized drug beyond the mention that research is underway in a particular area, in which case, the regulatory status should be indicated (i.e., market authorization not yet obtained), and no reference is made to the availability of unauthorized drugs through the Special Access Programme. No drug manufacturer's name is included.	Do not mention a particular drug or device. Do not include any representation or suggestion relating to a particular drug or device.	Therapeutic category including classes but no reference to a specific prescription product.	No mention of or hinting at the name of a product. The name of the internet site will not contain the trade or generic name of the medicinal product.
Sponsor name	Source should be clearly identified on the publication itself.				Each web page should contain the text: 'The information is provided as a service to the public sponsored by (name of Marketing Authorization Holder), Ministry of Health approval required in the case of DA campaigns conducted for diseases for which there is only one product approved, such as HIV or cancer.'
Only one approved product	When only one, one leading or few medicinal treatments available, particular care is required and it is particularly important that these DA campaigns focus on health and disease education with details of where to get appropriate advice.		Where the company is the only manufacturer of a product for a particular disease or the company only manufactures one product, that company is not automatically disqualified from disseminating communications that discuss a disease related to the product.		
Channel					Regulation defines permitted means of communication, including internet websites and social media networks and any other means of electronic communication.

Appropriate content

Along with clear intent goes appropriate content. Material should be accurate, up to date, substantiable, sufficient, balanced and fair (Table 1). In addition, the message should be tailored to the audience, their needs and perspective. Information should be understandable, relevant, helpful and adapted to the local context and specificities. Association with a specific product through use of color and look and feel of the campaign must be avoided, as that would be considered covert promotion. Use of appropriate tone could be tested by relevant patient groups or lay public advisory boards.

Recommendations

- Ensure campaigns speak the right language and use the right images for the audience (avoid ‘scare’ effects).
- Use clear lay language conveying relevant, balanced and accurate information.
- Do not use branding such as logos or look and feel of product advertising.
- Provide a complete picture, also including other preventative options or therapies besides vaccination alone, if applicable.
- Have a medical expert approve the content to ensure it reflects the most up-to-date medical knowledge.

Use of persuasion

DA campaigns need to be engaging and impactful to trigger action and result in a public health benefit. Appealing to emotion through stories that the public can identify with in order to persuade them to change behavior or seek a healthcare service need to be balanced. Emotive campaigns can cause harm if they generate fear and alarm and may even have the opposite effect by detracting from the message’s credibility. They can result in bias if based on selective or inaccurate information.²⁶ The use of emotion must be proportionate to reflect the factual seriousness of the condition described.

Recommendations

- Do not exaggerate benefits or harms, be proportionate.
- Be clear about which group within the general public stands to benefit from the intervention, and invite them to seek advice from HCPs.

Stakeholder engagement

While patients or the lay public should be engaged in reviewing DA campaign materials as mentioned in the first recommendations, other stakeholders also should be identified from an early stage. Patient organizations may provide helpful advice in identifying and addressing the needs of patients. HCPs, authorities and governments should be informed or given the opportunity to be involved in the development of vaccination awareness campaigns, so that they can anticipate the demand on services and nature of enquiries that may be prompted by the campaign. If a procedure is not covered by the state, payers

must be prepared for the campaign. HCPs and patient organizations may themselves have education needs with respect to the topic of the campaign.

Recommendations

- Identify and engage broadly with stakeholders from the earliest stage of the campaign’s development.
- Inform professional associations/societies of HCPs and authorities so they can anticipate questions from the public arising from the DA campaign.
- Ensure local appropriateness, as culture and perception may vary between countries.

Transparency on sponsorship

A transparent declaration that the campaign is financed by a biopharmaceutical company is required in most guidelines (Table 1), except in Canada, where rules for what they refer to as ‘help-seeking information’ specify that the sponsoring company’s name may not be included.⁵ The target audience must be given the opportunity to form an opinion in full knowledge that a commercial company is delivering the campaign.

Where a DA campaign is related to a condition for which the sponsoring company is the only one with a product on the market, concerns about DA activities being a covert form of advertising become relevant. In this particular context, the MHRA Blue Guide recommends that ‘extra care’ is needed. Similarly, the now-withdrawn FDA draft guidance mentioned that the company is not automatically disqualified from conducting a DA campaign in that situation, provided it does not implicitly identify a particular drug or device. In Canada, help-seeking announcements should not imply that a drug is the sole treatment available. Alternative preventative measures besides vaccination may also exist and should be mentioned.

Recommendations

- Clearly and transparently acknowledge sponsorship.
- Take extra care not to ‘product point’, i.e., refer to the specific characteristics of a product, when there is only the sponsoring company’s vaccine on the market in question.

Collaborations with not-for-profit organizations (NPO)

Consumer perceptions of DA campaigns have been reported as more positive if they are sponsored by an NPO than if by a commercial entity, suggesting that messages about a disease or health condition carry less weight if co-sponsored by a biopharmaceutical company.¹⁷ HCPs in India feel that pharmaceutical industry DA campaigns need to be co-sponsored by an NPO to give the communication a sense of impartiality.²⁷ But for the same reason, NPO-industry co-sponsorship can be perceived as misleading because it may blur the line between sponsored vs non-sponsored content.^{5,17,18,28}

Recommendation

- Only collaborate with an NPO when it adds benefit for the patient and society, for example if the NPO has a better outreach to the target audience or better understanding on how to communicate the message effectively.

Measurement of success

As stated above, the primary aim of DA campaigns is to benefit the public, patients, and population health in general by informing and increasing knowledge of how to prevent or treat diseases. For this reason, measurements of campaign success should reflect measures of individual and societal benefit, in terms of addressing knowledge gaps in the target audience, or in associated public health outcomes. Social media and websites offer opportunities to measure levels of public engagement by capturing metrics on how often posts are shared, commented on and liked, and how many times links are clicked. In the US, DA campaigns on social media reportedly show high levels of consumer engagement.²⁹ However, research studies evaluating the effectiveness of health awareness campaigns sponsored by governments or not-for-profit organizations indicate a variable impact on increased information seeking behavior between campaigns.^{30,31} Social media engagement and information seeking behavior were used as proxy for the public's increased understanding of a disease in those studies. Surveys and 'social listening' of mentions on social media around the disease topic can be used to learn about the impact of the campaign in the context of the wider information environment. Further studies of measurement of success of DA campaigns' impact on public awareness should be encouraged.

Recommendations

- Measures of DA campaign success should be in line with non-promotional intent, e.g., digital measures of public engagement with the campaign, by metrics of social media interactions and visits to webpages mentioned in the campaign.
- Use surveys of target audience, and/or social listening, to assess impact of the campaign and understanding of the message.
- Refer to independent, e.g., government or state, HCP data showing uptake of the relevant healthcare against their public health goals.
- Success could also be measured by HCP surveys on increase in questions from their patients and whether the message is recalled correctly.

Conclusions

In this paper, we establish recommendations to guide the ethical conduct of industry-sponsored Vaccination Awareness Campaigns (VACs) directed toward the general public based on GSK experience. A summary is provided in Box 1. Industry sponsored VACs should be part of

Box 1. Key recommendations for Vaccination Awareness Campaigns (VACs).

- Be clear about the non-promotional intent, with messages addressing audience's identified needs.
- VACs should not be conducted concurrently with branded campaigns for HCPs.
- Use lay language conveying relevant, accurate and balanced unbranded information.
- Engage broadly and as early as possible to involve and inform patients, healthcare professionals and authorities, ensuring preparedness and local appropriateness.
- Clearly and transparently acknowledge sponsorship.
- Do not 'product point', i.e., refer to the specific characteristics of a product.
- Collaborate with not-for-profit organizations when it adds benefit for the patient and society.
- Do not exaggerate benefits or harms, be proportionate, and invite the target audience to seek advice from healthcare professionals.
- Use digital metrics and surveys to measure the success of VACs.

a broader effort together with governments and public health institutions to address public information needs on the prevention of infectious diseases. We invite companies to share their experiences with a view to strengthening the public health impact of industry sponsored DA campaigns.

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Contributors and sources

Clair van der Zee had the original idea for the manuscript and wrote the first draft. All four authors are responsible for the intellectual content of the manuscript which they critically reviewed and edited, and they approved the final version.

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