BJCP British Journal of Clinical Pharmacology

DOI:10.1111/j.1365-2125.2008.03283.x

Direct-to-consumer information in Europe: the blurred margin between promotion and information

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Keywords
direct-to-consumer advertising (DTCA), promotion, information

Received
17 April 2008
Accepted
5 August 2008

During the last year, many papers in scientific journals have commented on the possible removal of the ban on direct-to-consumer advertising (DTCA) of prescription drugs by the European Parliament [1–3]. The promotion of prescription drugs directly to the public is currently allowed only in the USA and New Zealand. The risks related to this decision are brought into focus, especially if we consider the situation in the USA, where DTCA has been permitted since 1997.

Drug company spending on DTCA in the USA has increased twice as fast as spending on promotion to physicians or on the research and development of new drugs. According to publicly reported data, from 1997 to 2005 spending on DTCA increased by almost 20% each year. Over the same time period, spending on drug promotion to physicians and on research and development each increased by about 9% annually [4]. In 2005, drug companies spent in the USA $4.2 billion on DTCA and $7.2 billion on promotion to physicians. The same paper reports that one study on 64 drugs found a median increase in sales of $2.20 for every $1 spent on DTCA. Many publications have confirmed that DTCA influences patient demand and doctor prescribing behaviour.

Doctors typically acquiesce with patients who request drugs that they have seen advertised, and this increases both population drug-use rates and healthcare costs. Many concerns have been raised about the positive effects of DTCA on public health, particularly if prescribing appropriateness is considered. [5, 6]

Concerns about DTCA in the USA have recently been raised. Senators Edward Kennedy and Michael Enzi made a legislative proposal to prohibit the DTCA of prescription drugs in their first 2 years on the market [7, 8]. However, the proposal has not yet been approved.

In New Zealand, general practitioners demanded a ban on DTCA; they 'are particularly upset by the misleading content of many of the advertisements and the commercial pressure this puts them under to prescribe advertised drugs, even when they're no better than existing alternatives or are not suitable for the patient' [9].

Negative comment on DTCA has also come from the World Health Organization (WHO). A unanimous recommendation to prohibit DTCA was made during the 30th Annual Meeting of Countries participating in the WHO Programme for International Drug Monitoring in October 2007 in Buenos Aires [10].

The European Commission, however, denied any intention to remove the ban of the DTCA. Replying to an editorial published in the *Lancet* in January 2007 [2], the spokesman for the vice president of the European Commission, Gunter Verheugen, stated that, 'the Commission is not planning to propose any changes to the existing rules governing the advertising of prescription drugs', and announced a review of the existing provisions on information on medicinal products, which 'will not have an effect on advertising' [11].

A first public consultation on the provision of information to patients on medicinal products was launched by the European Commission in April 2007, and the results of this consultation have been available since October 2007 on the Commission's website [12].

In February 2008 the Commission, disregarding the negative comments received on direct information to patients, launched a new consultation on 'Legal proposal on information to patients', which terminated in April 7 [13]. The purpose of the Commission is 'to ensure good-quality, objective, reliable and non promotional

information on prescription only medicinal products to citizens and to harmonize the existing situation in Member States in this area'. The proposal, giving the clear safeguard that all advertisement to the public is banned, might enable the pharmaceutical industry to 'inform' patients directly on prescription medicines using the internet, TV, radio, printed material actively distributed, etc.

At the end of May 2008 a summary of the outcome of the consultation, together with most of the received responses, was published on the Commission website [14].

One hundred and ninety-two contributions were received (a more than twofold increase compared with the 73 replies to the first consultation), representing almost all the involved players in the drug issue, mainly divided into healthcare professionals and organizations (32%), patients' organizations (22%), regulators (15%) and pharmaceutical companies/organizations (14%).

There was overall consensus that there is a need to provide patients with understandable, objective and high-quality information on drugs. Almost all the replies, as in the previous consultation, reported opposition to the removal of the DTCA ban in Europe, making sure that there is a clear distinction between advertising and nonpromotional information. However, only one-third of the responders (but all the pharmaceutical companies/organizations) highlighted the role of industry as a source of nonpromotional information.

Some comments on this consultation have been recently published, mainly focusing on the blurred margin between drug information and promotion [15–17].

The key issue in analysing the role that industry could have in the provision of direct information to patients is of having clear definitions of and a clear legal distinction between information and advertising.

The public consultation introduces a distinction between information passively received by the patient ('push') and information actively searched ('pull'). According to the proposal, all 'pulled information' (such as internet searches, seminars and responses to patient-specific requests), together with specific 'pushed information' (such as TV and radio programmes with factual content or printed material actively distributed to citizens), should be possible, according to specific quality criteria.

We believe, however, as do many other responders, that in a market that is becoming increasingly competitive, scepticism is warranted on the possibility of a pharmaceutical company offering objective and nonpromotional information on its products, irrespective of quality, without promoting them. Most of the allowed 'patient information' in the proposal appears to be advertising under a different name.

Professor Robin Ferner, replying to the consultation as Chair of the Clinical Pharmacology Section of the British Pharmacological Society, has said that 'while there may be ethical and public-spirited attempts by pharmaceutical companies to improve the public health, there is also evidence or suspicion of unethical or dishonest practices that are counter to the desire for rational, effective, and cost-effective use of medicines for the benefit of the community'.

Another important issue is the proposed structure for monitoring and sanctions. Who should monitor industry information and, if violations occur, apply sanctions? In countries where DTCA is allowed (i.e. in the USA), authorities have often failed delaying controls and sanctions. In the Commission's proposal it is stated that sanctions should be imposed to drug companies by each Member State only 'in the case of repeated and severe case of non-compliance'. Furthermore, monitoring activities will be more complicated in the future if we consider the increasing importance of digital satellite television and the internet.

The importance of the internet is in our opinion often underestimated. The Commission published in April 2007 a document to introduce the consultation on information to patients, where the use of the internet and other innovative technologies is discussed [18]. In this document the Commission states that 'the internet differs from more traditional forms of communication' mainly because 'it requires active action from users before information is available to them. This can specifically influence the distinction between advertising and information'. The implicit conclusion is that since the internet requires interaction with the user, no advertising is possible without the user's consent. The worldwide web, as anyone will notice in a few seconds' surfing, is indeed filled with inescapable advertising. Advertising on the internet includes not only automatic pop-ups, but also strategies to promote websites by increasing their visibility in search engine result pages.

The internet is becoming increasingly important in the advertising market. For the full year 2007, internet advertising revenues in the US totalled $21.2 billion, exceeding 2006 performance by 26 %, itself the former record year [19]. The North American search engine marketing industry grew from $9.4 billion in 2006 to $12.2 billion in 2007, and is now projected to grow to $25.2 billion in 2011 [20].

Limits on the information available on the internet are well recognized and they include reliability and quality of the provided information, accessibility of the information for selected groups (e.g. elderly, disabled), availability and the knowledge of the informatics hardware and software. However, the important difference between the internet and other sources of information is that the internet transcends country boundaries and for this reason is more difficult to control and regulate.

A recent study has reported that pharmaceutical websites are unlikely to communicate risk information completely [21]. Another study on the quality of the top 50 websites on schizophrenia concluded that 'the documented influence of the pharmaceutical industry over research, professional organizations, teaching institutions, clinical practice and regulatory bodies may now extend to

public promotion, via the internet, of perspectives conducive to maximize sales' [22].

Despite methodologies to assess the quality of patient information, such as the Ensuring Quality Information for Patients tool, have been recently discussed and developed [23], the conflict of interest for pharmaceutical companies to give nonpromotional information seems to be overwhelming. For this reason, the limits imposed on industry by the European Directive 2001/83 (particularly articles 86 and 88) should not be weakened. Industry should limit their activities in this field to improve quality, clarity and understanding of drug leaflets, which represent a very important source of information for consumers and should be harmonized through European countries. Initiatives to facilitate access to patient information leaflets and other approved product information do not require any changes to the actual legislation.

The Commission should also work to improve the range, availability, clarity and particularly the quality of independent and unbiased information in Europe.

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