

Direct-to-consumer advertising of prescription drugs: harmful and difficult to regulate

- The United States Congress has criticised the FDA for its inability to effectively regulate direct-to-consumer advertising of prescription drugs.

- Delay in issuing regulatory letters, lack of systematic criteria, and inadequate resources: these are some of the failings that allow drug companies to get away with misleading advertisements.

- The only effective way of protecting the public from direct advertising of prescription drugs is to simply ban it.

A US report evaluated the effectiveness of administrative controls on direct-to-consumer advertising (DTCA) of prescription drugs (1). Such ads are currently authorised in only two countries: the United States and New Zealand. DTCA has been shown not only to increase drug sales, but also to have a negative impact on public health (overconsumption of some drugs, inappropriate choices of drugs, etc.) and on healthcare spending (a)(2-6).

According to several studies, one dollar invested in DTCA for prescription drugs can generate up to 6 dollars in extra sales (1). In the USA, drug companies' budgets for direct-to-consumer advertising are rising more rapidly than their budgets for ads targeting prescribers or for pharmaceutical R&D (1).

Ineffective regulatory controls

The Government Accountability Office (GAO) of the United States Congress (b) examined how the Food and Drug Administration (FDA) regulates direct-to-consumer advertising (1).

Only eight FDA employees are specifically responsible for the regulation of direct-to-consumer advertising, on TV, radio, the Internet, and in print (1).

The FDA is only able to regulate advertisements after ad campaigns have already been launched, as is the case of ads targeting healthcare professionals in France. If a violation is detected, the FDA then sends the company a regulatory letter, telling it to stop running the advertisement or, in more serious cases, to disseminate a corrective message about the issues discussed in the regulatory letter. After receiving a regulatory letter from the FDA, the company has two weeks in which to explain in writing how it intends to comply. The company can be prosecuted if it fails to do so (1).

It takes several months for the administration to react to new advertising campaigns. The FDA is supposed to receive copies of all advertisements as soon as they are disseminated (broadcast, print or Internet ads) (1). Companies are also supposed to submit their draft advertisements for scrutiny before distribution, but this rarely happens.

The number of advertisements submitted to the FDA increased from about 7000 in 1999 to more than 15 000 in 2005 (1), yet the number of FDA regulatory letters sent to companies for misleading advertisements fell from 25 in 1998 to 8 in 2005 (1).

Similarly, the interval between the dissemination of a misleading advertisement and the FDA regulatory action increased

from two weeks before 2001 to more than 4 months in 2002... and to 8 months on average in 2005 (1).

This resulted from a modification in procedures in 2002, requiring the FDA to first submit its draft regulatory letters to its legal department (1).

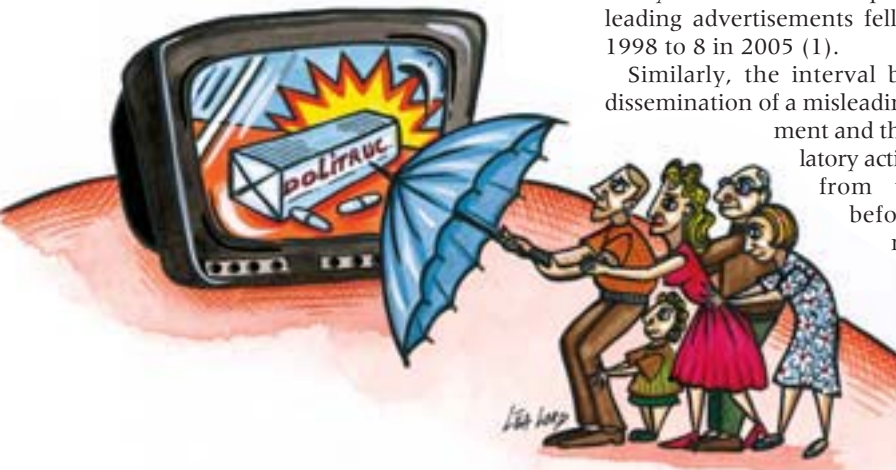
In view of the number of advertisements that need to be reviewed, the GAO criticised the FDA for failing to establish a set of criteria with which to give priority screening to advertisements that are most likely to be misleading (1). The FDA explanation is that it focuses on ads that have the greatest potential impact on the public (mainly TV ads) but it doesn't apply standardised criteria. The FDA therefore cannot guarantee that it regulates all advertisements with the greatest potentially negative impact on patients (1). In addition, the FDA has no record of the advertisements it has reviewed (1).

Ineffective FDA regulatory procedures. The GAO also highlighted the ineffectiveness of FDA procedures designed to prevent the dissemination of inaccurate and misleading advertisements (1). The GAO examined 19 FDA regulatory letters, concerning 31 advertisements, sent to companies in 2004 and 2005 (1). In 16 cases, the advertising campaign had ended by the time the FDA sent out its letters. The other ads were withdrawn when the regulatory letter was received, but the product had already been promoted for an average of 8 months (1).

In the 10 out of 19 cases in which the FDA requested a corrective advertisement, i.e. those involving the most serious violations, the companies only released the corrective advertisements 5 to 12 months after the FDA issued the letters (1).

The GAO finally noted that FDA regulatory letters fail to deter companies from releasing new advertisements that sometimes make the same misleading claims (1).

Recommendations to FDA for improvements in regulatory controls. Despite this appalling situation, the GAO's recommendations are limited to the strict minimum: standardising the criteria used to identify advertisement that should receive priority; implementation of these criteria; and recording of all advertisements that have been reviewed (1). In its response to the GAO,



the US Department of Health and Human Services accepted the criticisms but challenged the recommendations. According to the FDA, although the criteria used to prioritise advertisements are not standardised, they are nevertheless systematically applied. Moreover, according to the Department of Health and Human Services, implementing these recommendations would require a substantial increase in staff (c)(1).

The only effective preventive measure: an outright ban on DTCA

The negative impact of drug advertising on public health and healthcare expenditure is well established, whether the advertisements target healthcare professionals or the public. It is unrealistic to believe that DTCA can be effectively regulated, due to administrative delays, inadequate funding, and the fact that FDA regulatory action is only taken after ad campaigns have already been launched. We've observed a similar situation over the years in France concerning bans

issued by the French Health Products Safety Agency (Afssaps) on ads targeting healthcare professionals. The GAO report confirms that this is also the case for direct-to-consumer advertising.

The US report is particularly welcome, as it comes at a time when pressure is again being exerted in Europe to authorise direct-to-consumer advertising for prescription drugs, under the guise of "health information" (d).

An editorial in *The Lancet* compared DTCA to a "genie" that should not be let out of the bottle (7).

The only way the authorities can protect citizens from the negative effects of this drug advertising is to continue to ban it.

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a- For further information on the impact of DTCA, see the references in reference 8.

b- The Government Accountability Office (GAO) is an agency that works for Congress. It is charged with auditing, evaluating and investigating the use of public money, and policies and programmes of the federal government (ref 1).

c- It was finally decided to increase staffing, with salary costs paid through a substantial increase in company dues (ref 9).

d- See "The European Commission's proposal on information to patients" will boost drug sales not serve patients' interests" www.prescrire.org/cahiers/dossierEuropeMedOpenLetter3EN.php.

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Standing up to salt industry lobbies

● Health professionals and researchers can successfully fight misinformation.

Why would a scientific researcher working in the public interest not seek to publicise results with important implications for public health?

Pierre Meneton, a researcher at INSERM, the French Institut National de la Santé et de la Recherche Médicale, decided to draw attention to the cardiovascular risks associated with excessive salt consumption (1).

International guidelines on salt intake agree on the need to inform the public of the dangers of excessive salt consumption, and for information on salt content to be systematically provided on the labels of processed foods (1-4). Yet these recommendations are largely ignored in France (1).

Countering misleading information. Pierre Meneton decided to denounce the "information" issued by the salt industry, and the ineffectual responses of the French authorities under the influence of food processing industry

lobbyists, as well as the lack of necessary regulations such as systematic labelling of processed foods (1,5).

In 2007, Pierre Meneton was taken to court by the salt industry, via the Comité des Salines de France (Salt Producers' Syndicate of France), who accused him of libel when he claimed (our translation): "Lobbyists for the salt and food processing industry are very active. They misinform healthcare professionals and the media" (6).

The right and obligation to blow the whistle. Pierre Meneton, far from being intimidated, decided to use the trial to air his point of view. The court ruled in his favour, pointing out that lobbies simply defend their vested interests. The court also stressed that, as a researcher, Pierre Meneton had a right and even an obligation to challenge the salt lobby in good faith (a)(7).

The court's decision supports independent scientific analysis.

Others should follow this outspoken researcher's example and be willing to argue their position without waiting for a law to protect whistle-blowers (8). Pierre Meneton's case illustrates that

Selected references from Prescrire's literature search.

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5- Toop L et al. "Direct to consumer advertising of prescription drugs in New Zealand: for health or for profit?" Christchurch, Dunedin, Wellington and Auckland Schools of Medicine 2003. www.chmeds.ac.nz accessed 3 October 2007: 95 pages.

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9- Koroneos G "PDUFA passed with refined DTC component". www.pharmexec.com accessed 2 October 2007: 2 pages.

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a- Direct testimony: members of the Prescrire team attended the hearing.

1- Meneton P "La lutte contre l'excès de sel alimentaire" *Rev Prescrire* 2004; 24 (248): 232-233.

2- Prescrire Editorial Staff "Adult hypertension: reducing cardiovascular morbidity and mortality" *Prescrire Int* 2005; 14 (75): 25-33.

3- Prescrire Rédaction "Alimentation des enfants: des salières sur la table de la cantine scolaire?" *Rev Prescrire* 2005; 25 (259): 236.

4- Prescrire Rédaction "Sel et événements cardiovasculaires" *Rev Prescrire* 2007; 27 (290): 927.

5- Cattan P "Scandale alimentaire. Sel: le vice caché" TOC du 18 March 2006: 14-15.

6- AFP "Les méfaits du sel sur la santé au centre d'un procès en diffamation" Release 31 January 2008: 1 page.

7- AFP "Les producteurs de sel perdent leur procès contre un chercheur de l'Inserm" Release 13 March 2008: 1 page.

8- AFP "Des scientifiques demandent la protection des lanceurs d'alerte" Release 29 January 2008: 1 page.