

Direct-to-consumer advertising (DTCA) of prescription medicines: fourth quarterly update - October to December 2002

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Introduction

This report is the fourth quarterly update for 2002 tracking developments in direct-to-consumer advertising of prescription medicines in Europe and the US (see earlier updates for details).

This is the final regular update on DTCA to be produced for the RPSGB.

Summary of key developments for this quarter

- The European Parliament rejected the European Commission's proposals to permit advertising of prescription medicines for certain conditions to the public (part of the broad review of EU medicines legislation).
- The European Parliament committee with lead responsibility for the review of EU medicines legislation also rejected the Commission's proposals.
- The Pharmaceutical Research and Manufacturers of America (PHRMA) published a new report outlining the benefits of DTCA.
- UK advertisers sponsored a meeting in the House of Commons on public access to information at which the issue of DTCA of pharmaceuticals was debated.
- HealthWatch published a position paper on DTCA strongly opposing its introduction, but recommending that if DTCA were to be allowed it should begin cautiously and only if systems of self-regulation can be made fully effective.
- Cambridge University Health (CUH) held a number of Expert Panel discussions as part of its *Informed Patient* project. The project will directly inform the broad review of EU medicines legislation.
- The US General Accounting Office (GAO) published its new report *Prescription Drugs – FDA Oversight of Direct-to-Consumer Advertising Has Limitations*.

Regulatory developments in the EU and the UK

The fourth quarter of 2002 saw two significant developments in the European Union. Firstly, the European Parliament (EP) debated the European Commission's (EC) proposals on the provision of information to patients contained within the broad review of EU medicines legislation. Secondly, the committee with lead responsibility for the review also concluded its debate on the Commission's proposals and voted to reject them.

- Developments within the EU

The European Parliament's Committee on Environment, Public Health and Consumer Policy vote

This committee has lead responsibility for the broad review of EU medicines legislation. After a long debate on October 2nd 2002, the committee voted to reject the Commission's proposals by 33 votes to 18.

As an alternative to the EC's proposals on DTCA, the committee suggested that the EC should draft a comprehensive patient information strategy to ensure that good quality, objective and reliable information is made available. The committee said this information should be non-promotional.

The European Parliament debate and vote

On October 22nd the EP debated the EC's proposals on information for patients for the first time. The EC's proposals were rejected by an unexpectedly wide margin of 494 votes to 42.

During the debate in Strasbourg the European Commissioner responsible for Enterprise, Erkki Liikanen, told the Parliament that the proposal would mean that patients had controlled access to information from the companies. He said: "Our proposal is that European citizens should obtain information that has been validated by European regulatory authorities".

Opposing the EC proposal, Labour health spokeswoman Catherine Stihler said the EC's plan was a move towards American-style mass advertising. She said Europe was at a crossroads and had to decide if it wanted to go down the 'slippery slope' towards hard-sell drug advertising as seen in the US.

Reaction - The European Commission

The EC then issued a statement on the EP vote. The Commission gave a 'qualified welcome' to the EP vote to reform European legislation on pharmaceutical products. However, it said it hoped agreement can soon be reached on a number of issues including the provision of better information for consumers. It said: "Swift action is

necessary to ensure that patients have access to innovative medicines and to high-quality information on these products”.

European Commissioner Erkki Liikanen said that the proposed reform of Europe’s pharmaceutical legislation will provide great added value for Europe’s citizens by increasing the availability of innovative medicines while favouring competition with generics. However, he also warned that there are outstanding points needing further discussion. He said:

“I regret that the European Parliament today rejected our proposal to allow patients suffering from AIDS, asthma or diabetes to be able to get information on medicines used to treat these diseases from the pharmaceutical companies that manufacture them. Our proposal would not allow non-solicited advertising for such medicines – as is the case in the United States. But it would enable these patients to get good, appropriate and officially authorised information if they so request. Patients interested in such information today generally find it via the Internet from US based web-sites. Obviously, not all Europe’s patients have access to the Internet or understand English. Also, as medicines marketed in the US are often not identical to those marketed in the EU, even if they bear the same name, this might even constitute a health risk. We must therefore ensure that the information for which there is a strong demand is available to all Europe’s patients, that it is correct, appropriate, and authorised by the European Medicines Evaluation Agency in London so patients in Europe are better informed. Nothing is further from our minds than introducing advertising for prescription medicines in Europe. What we are proposing is to allow Europe’s patients to obtain appropriate and authorised information if they ask for it.”¹

Reaction - The Association of the British Pharmaceutical Industry (ABPI)

The ABPI said it welcomed the EP’s decision. The association has argued that the Commission’s proposals did not go far enough as they would only allow companies to communicate directly with patients with AIDS, asthma and diabetes.

The ABPI also said that it has not sought to change regulations to permit the advertising of prescription only medicines directly to patients. It added: “However, the industry still firmly supports the principle of being able, in a properly regulated environment, to provide reliable and quality information about medicines directly to patients, carers and the public. Anyone else can supply information about medicines to patients – but those who know most about them, the pharmaceutical companies, are forbidden by law from doing so”.²

The Association added that current restrictions preventing the industry from communicating directly to the public are a form of out-dated censorship.

¹ EC Statement: Commission gives qualified welcome...IP/02/PHARMA VOTE-EN, 23rd Oct 2002

² ABPI Welcomes European Parliament Decision on DTC. Press Release. Oct 23, 2002.

Reaction - The Pharmaceutical Group of the European Union (PGEU)

The PGEU represents community pharmacists in 28 European countries. It welcomed the EP vote. It said the EP has recognised that medicines are special products and that they should not be treated like normal consumer goods.³

In its response the PGEU said: "The PGEU is convinced that objective, unbiased and comprehensive information on medicines and health issues have to be guaranteed to all citizens. Therefore a clear distinction between information and advertising has to be maintained".

Reaction - Health Action International (HAI)

HAI (the body that co-ordinated opposition to the EC proposals) welcomed the decision. It said that if the plans were introduced they would have weakened the EU's ban on the advertising of prescription only medicines to the public. It said: "The industry and DG Enterprise have repeatedly tried to disguise this advertising effort as a way to inform patients about their medicines. However, the Parliament clearly saw the proposal's actual intent and defeated it".⁴

The future of the review and the Commission's proposals

Following the vote the EC confirmed that the proposals on reform of European legislation on pharmaceutical products will now go to the EU's Council of Ministers before going back to the EP for a second vote. The reform package is contained within one EU Regulation and two Directives.

- Proposal for a European Parliament and Council regulation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.
- Proposal for a European Parliament and Council directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.
- Proposal for a European Parliament and Council directive amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

The proposals are available at: <http://pharmacos.eudra.org/F2/review/index.htm>

Other Developments in Europe

The Debating Group tackles patient information

The UK television and advertising industries are stakeholders in the debate about DTCA and until recently have said little publicly about the issue. However, in October 2002 the

³ European Parliament recognises the special nature of medicines. PGEU Press Release. Oct 24, 2002.

⁴ European Parliament soundly rejects move towards direct-to-consumer advertising, HAI Europe applauds Parliament's decision to protect public health, not industry's interests. HAI Europe Press Release. Oct 24, 2002.

media and communications forum The Debating Group held a debate on public access to information about medicines in the House of Commons chaired by Austin Mitchell MP. The debate was well attended and addressed the following motion: "The barriers to communication of information about prescription medicines damage public health".

The debate was sponsored by the Advertising Association, Chartered Institute of Marketing, Commercial TV, Direct Marketing Association, International Advertising Association, IPA/44 Club, JICREG, Marketing Research Society, Periodical Publishers Association and the Publicity Club of London. Most of those who attended represented advertising interests.

The Director General of the APBI, Trevor Jones, and the Director of the Patients Association, Mike Stone, spoke for the motion. The Chair of the All Party Parliamentary Group on Pharmacy Dr Howard Stoot MP and Director of Campaigns for the Consumers' Association Allan Asher spoke against. During the debate those opposing DTCA of medicines criticised the wording of the motion claiming it was deliberately confusing. The motion was carried by a large margin.

HealthWatch position paper on direct-to-consumer advertising published

In December 2002 HealthWatch published its position paper on DTCA claiming that promotion direct to consumers was a bad idea but that if it is introduced then it needs rigorous control. HealthWatch is a registered charity that promotes evidence-based assessment of all forms of treatment. Its objective is to provide the public with reliable information about healthcare. Its members include scientists, clinicians, lawyers and journalists.

President of HealthWatch and broadcaster Nick Ross drafted the paper along with the HealthWatch Secretary Michael Allen (a pharmacist who worked for 26 years in pharmaceutical regulatory affairs).

The position paper describes how the promotion of prescription medicines has always been banned in the EU. However, it outlines how patients have access to many sources of information on medicines other than their own doctor including newspapers, television, official helplines, health charities and support organisations and the internet. The authors say that the global nature of the internet makes DTCA difficult to regulate because it is permitted in the US.

HealthWatch says that while it supports free expression as a general principle and believes that reliable information is more likely to emanate from openness than from over-regulation, it also argues that medicines have several features that distinguish them from other goods and services.

The position paper also states that while pharmacists and doctors control access to prescription medicines they are also influenced by patients. The paper states: "The hard-headed pharmaceutical industry does not spend hundreds of millions of dollars each year in the US for no return; they invest heavily in DTCA because they know consumers exert huge and effective pressure on prescribers".

The paper also states that HealthWatch is strongly opposed to the introduction of DTCA. However, if it is introduced then it should be started cautiously and only if systems of self-regulation can be made fully effective. The paper outlines a set of proposals to bolster the regulations proposed by the EC. These include:

- regulations ensuring that 50 per cent of DTCA spend would be on substantive advertising, defined as explanatory text, which allows consumers to make reasoned judgements;
- advertisements should include other information to enable patients to make an informed choice including a summary of the patient information leaflet;
- where a company gives financial support to a patient group or other organisation operating in a field where the pharmaceutical company's products may be used then the link should be transparent.

The Informed Patient

In November 2002 Cambridge University Health (CUH) held a number of Expert Panel discussions as part of its *Informed Patient* project. The project will directly inform the Review of the Regulation of the Pharmaceutical Industry by the European Union. It is also being used to inform national debates on engaging the patient in the health system of their country and encouraging the public in their own health management.

The Expert Panel sessions were organised to allow discussion on key topics with experts from stakeholder groups. The main focus was on the benefits of providing information to patients and how this affects their healthcare and other aspects of their life and the economy. The potential benefit or harm in allowing pharmaceutical companies to provide information in the form of advertising was a key discussion point. Eileen Neilson represented the RPSGB on one of the panels.

The objectives of the *Informed Patient* project are:

- to explore the perspectives relevant to patients getting all information they need to be fully engaged in the management of their own healthcare;
- using these perspectives, advise the policy process with respect to management of information for patients in an Information Age.

Cambridge University Health is the Health Policy and Management Centre for the University of Cambridge and brings together expertise from across different schools in the University of Cambridge. The project is co-ordinated by Professor Don Detmer who is the Director of CUH and Dennis Gillings Professor of Health Management at the Judge Institute of Management at the University of Cambridge.

Cambridge University Health has circulated a summary of the issues raised at the professional Expert Panel held in November 2002. These summaries are not attributed to any of the individuals who attended.

Developments in the US

PHRMA Publishes New Report on DTCA

In October 2002 the Pharmaceutical Research and Manufacturers of America (PHRMA) published its a report on the marketing of prescription only medicines – *Direct-to-Consumer Advertising Strengthens Our Health Care System*. The report concludes that direct-to-consumer advertising:

- improves the patient–physician relationship;
- is valuable to patients;
- helps balance efforts from other healthcare participants, such as managed care plans, to influence the delivery of healthcare; and,
- increases pharmaceutical utilization.

PHRMA says that DTCA helps patients talk to their doctors about their conditions and treatment options. It says DTCA encourages patients to talk to doctors for the first time about certain conditions, improves patient compliance with treatment regimes and can help patients understand the information about risks and side effects.

The report also argues that DTCA makes consumers aware of new drugs for diseases and helps tackle the problem of undertreatment and underdiagnosis of disease which it says is a particular problem in the US.

PHRMA says some managed care plans are attempting to influence the delivery of medical care by offering payment incentives linked to specific prescribing patterns or formularies. The report says: “In light of these strategies designed to influence the medicines that patients receive, providing information to patients about their treatment options through DTCA is a healthy development that helps add balance to the system”.

The report concludes that if DTCA is stimulating demand for medicines then this is a good thing because “proper use of pharmaceuticals is often the most effective and least expensive form of health care”. PHRMA says DTCA’s purpose is to encourage an informed discussion between the patient and the physician.⁵

General Accounting Office Report On Pharmaceutical Advertising

In December 2002 the US General Accounting Office (GAO) published its new report *Prescription Drugs – FDA Oversight of Direct-to-Consumer Advertising Has Limitations*. The research for the report was launched after members of the United States Senate and the House of Representatives asked the GAO to:

- compare spending by pharmaceutical companies on DTC advertising with spending on all promotional activities and on research and development;
- evaluate the effect of DTC advertising on prescription pharmaceutical spending and utilization; and,
- evaluate the extent and effectiveness of FDA’s oversight of DTC advertising since FDA issued its 1997 guidance for broadcast advertisements.

⁵ www.phrma.org

For its research the GAO reviewed reports on trends in spending on DTCA, overall promotion, and research and development from the pharmaceutical industry and other organisations. It also reviewed studies on pharmaceutical sales, examined surveys of consumer responses to DTCA and reviewed studies on the impact of DTCA. To evaluate the extent and effectiveness of FDA's oversight of DTCA the GAO reviewed federal regulations, regulatory letters and interviewed officials from several different offices within the FDA including the Division of Drug Marketing, Advertising, and Communications (DDMAC) – the Division with responsibility for regulating DTCA promotion. GAO also interviewed representatives from industry, other stakeholders, public interest groups and representatives from the advertising industry. The research started in February 2002 and finished in September 2002.

The GAO's research found that:

- pharmaceutical companies spend more on research and development than on all types of promotion including DTCA;
- spending on DTCA has increased more sharply than the increase in spending on research and development;
- total promotional spending was equivalent to 12 per cent of drug sales in the US in 2001;
- DTCA appears to increase spending on prescription pharmaceuticals and utilisation;
- between 1999 and 2000, the number of prescriptions dispensed for the most heavily advertised products rose by 25 per cent, but increased by only 4 per cent for pharmaceuticals that were not heavily advertised;
- between 1999 and 2000, the cost of the most heavily advertised pharmaceuticals rose by 6 per cent while the increase for other medicines was 9 per cent; and,
- around 5 per cent of all consumers have requested and received from their physician a prescription for a pharmaceutical in response to seeing a direct-to-consumer advertisement.

On the FDA's role in halting the dissemination of advertisements it identifies as misleading the GAO found that:

- FDA's oversight has limitations;
- DDMAC focuses on advertisements that will be widely circulated or that are the most likely to impart misleading impressions of a medicine to consumers;
- the FDA issues regulatory letters concerning a small percentage of the advertisements it reviews;
- between August 1997 and August 2002 the FDA issued 88 regulatory letters concerning advertisements that violated FDA rules;
- FDA's oversight has not prevented some companies from repeatedly disseminating new misleading advertisements for the same products;
- some companies have failed to submit all advertisements for review by the FDA on time;
- in January 2002 new procedures have significantly increased the time between the identification of a misleading ad and the FDA's request to have it withdrawn;
- in 2002 some regulatory letters were issued after misleading promotional campaigns had finished.

The GAO concluded that DTCA prompts millions of people to ask their doctors for prescriptions for specific brand-name pharmaceuticals. It says that it is therefore important that the FDA act quickly to minimise the public's exposure to misleading advertisements. In its recommendations the GAO said that the FDA should speed up its review of regulatory letters.⁶

The full GAO report is available at: <http://www.gao.gov/new.items/d03177.pdf>

Datamonitor Report on Pharmaceutical Advertising

In November 2002 the independent market analyst Datamonitor published a report claiming that pharmaceutical companies are investing in marketing at a faster rate than the growth in sales. The firm concludes that the levels being invested in marketing are unsustainable.

Datamonitor's analysis shows that among the 14 top pharmaceutical companies average return on primary care physician and patient targeted promotion has fallen. This means that companies need to spend the same amount year after year to maintain sales. Datamonitor says the companies can't increase profit margins by spending more on advertising. To improve profits or shareholder value companies are forced to either 'cannibalise' investment in other operations to fund further promotion or merge with or acquire another company to expand the overall size of promotional funds.

Datamonitor concludes that promotional excellence and not the level of expenditure is driving commercial success. Some companies are seeing much higher rates of return from promotion than others.⁷

PharmTrends survey

The August 2002 PharmTrends survey (carried out by the market research company Ipsos-NPD and published in the fourth quarter of 2002) shows that DTCA is prompting more people to visit their doctor to ask about an advertised medicine: one in five Americans has responded to DTCA in this way.

Commenting on the new survey among 25,182 people, the director of the PharmTrends survey told the BMJ: "The information is still telling us that consumers are accepting and actually eager to find information about prescription drugs. Our results show that prescription drug advertising pays off, not only by enhancing branded prescription drug awareness and encouraging trial use but also by reminding patients to fill or refill their prescriptions".

The survey also found that:

- 22% of respondents said that DTCA made them aware of potential pharmaceutical options for their condition;

⁶ <http://www.gao.gov/new.items/d03177.pdf>

⁷ Pharmaceutical Giants Over-Invest in Promotion. Datamonitor Press Release. November 2th, 2002.

- 12% said that DTCA prompted them to ask their own doctor about a prescription medicine they saw advertised;
- 10% said that a DTCA advertisement reminded them to refill a prescription; and,
- 5% said they were prompted to switch from their current medicine to a different one that they had seen advertised.⁸

Other Development in the US

- The new FDA Commissioner Mark McClellan has promised faster action to stop pharmaceutical advertisements misleading patients, according to a report from Associated Press in December 2002. This news followed claims from the consumer advocacy organisation Public Citizen that warning letters sent to offending manufacturers have dropped by almost two thirds in one year.⁹
- Two former editors of the New England Journal of Medicine called for a ban on DTCA in December 2002. The call was made in a joint analysis of pharmaceutical regulation in the US.¹⁰
- In November the New York Times (NYT) published further evidence that public relations and marketing companies are expanding their role in the development of pharmaceuticals. NYT said the three largest advertising companies – Omnicom, Interpublic and WPP – have spent tens of millions of dollars to buy or invest in companies that carry out clinical trials. While company spokesmen say they are not interfering with the research process, critics claim that the marketing cannot be separated from the science.¹¹

⁸ BMJ 2002;325:854 (October 19th)

⁹ FDA Says it Will Stop Misleading Drug Ads. Associated Press. Dec 11, 2002.

¹⁰ Ex-NE Journal editors rip drug companies. Boston Herald. Dec 11, 2002.

¹¹ Madison Ave. Play Growing Role in Drug Research. New York Times. Nov, 22. 2002.