



## CHRONOLOGY: DIRECT-TO-CONSUMER ADVERTISING IN EUROPE

**August 1997** The US Food and Drug Administration relaxes regulations on medicine advertising on television, radio, and the internet.

**May/October 1998** The TransAtlantic Business Dialogue (TABD) issues its mid-year assessment in which it criticises the EU restrictions on DTCA (European ban on direct to consumer advertising) in comparison with the United States.

**October 1998** The head of the Pharmaceuticals Unit at DG Enterprise alludes to talks on ending the ban on DTCA at the annual meeting of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA).

**November 1998** TABD welcomes this announcement and the industry requests that the Commission establish a working group to review DTCA issues.

**April 1999** DG Enterprises Pharmaceuticals Unit and Pharmaceutical Committee agree on a definition of “interpretive guidance”, which attempts to make a distinction between medicines information provided by manufacturers and advertising.

**April 1999** A questionnaire is conducted by the Pharmaceuticals Unit at DG Enterprise to canvas opinion on DTCA issues. However, the results are never published.

**June 1999** The Commission publishes a proposal suggesting strict limitations on advertising medicines to the general public and allowing member states to prohibit any advertising of medicines that are reimbursed. However, the proposal still allows for some advertising of prescription only medicines directly to patients.<sup>i</sup>

**March 2000** The first consultation on DTCA is launched.

**March 2000** Philippe Brunet, DG Enterprise’s head of the Pharmaceuticals Unit writes to HAI Europe to explain that the unit is seeking input beyond the consumer bodies it traditionally consults. In the letter, Brunet suggests that HAI contact a representative from a patient group, which is later discovered to be founded by pharmaceuticals giant, Bristol-Myers Squibb.

**January 2001** The Commission organises a public hearing for stakeholders but there is no discussion on DTCA.

**March 2001** The Medicines High Level Group on Innovation and Provision of Medicines (G10), a think tank with large industry representation, meets for the first time.

**July 2001** In its review of pharmaceuticals legislation, the European Commission proposes changes to Article 88(2) of the pharmaceutical regulation to remove the legal restriction on DTCA in the framework of a pilot project on 3 diseases: asthma, AIDS and diabetes, .

**May 2002** The G10 recommends public-private partnerships and searching for a practicable distinction between information and advertising.

**October 2002** The European Parliament (EP) votes by a 12 to 1 ratio to uphold the full ban on DTCA in Europe, rejecting the attempt to introduce the pilot project and relax the advertising ban on prescription medicines.

**April 2003** Ignoring the EP vote, the Commission adopts amended pharmaceutical review proposals, including a pilot study.

**September 2003** The EU Council of Ministers rejects the Commission's proposal to weaken the ban on advertising prescription-only medicines to the public, as well as the pilot study.

**December 2003** As a compromise, the Council of Ministers and the Parliament ask for a report on current patient information practices in Europe to be published within three years.

**March 2004** Directive 2004/27/EC is adopted.

**June 2005** European Commission Vice-President, Günther Verheugen and EU Health and Consumer Protection Commissioner Markos Kyprianou set up the High Level Pharmaceutical Forum to follow-up on the G10 recommendations.

**March 2006** Five MEPs create the Patient Information Network (PIN), supported by pharmaceutical companies, and sign a letter calling on the European Commission to "step up its efforts to improve information to European patients", which sparks a new round of discussions on DTCA.

**September 2006** The High Level Pharmaceutical Forum meets for the first time in Brussels and establishes a working group on Information to Patients. In a speech to the Forum, Günther Verheugen says he "openly regrets" the Parliament's decision in 2003 to reject a relaxation of EU pharmaceutical advertising regulations for prescription-only drugs.

**October 2006** The European Parliament's Health and Consumer Intergroup meet in Brussels to discuss revisiting the EU ban on DTCA. MEP Jorgo Chatzimarkakis, member of the PIN, tells the

Intergroup that now is a good time to reopen the DTCA debate as many MEPs are new and were not involved in the earlier vote to uphold the ban.

**October 2006** A coalition of public health oriented NGOs launch a declaration to ensure that EU initiatives contribute to information that meets patients' health needs. It also underlines the promotional nature of any "information" prepared by manufacturers, due to their inherent conflict of interest, and denounce the moves to introduce advertising disguised as "information". The group also calls on the Pharmaceutical Forum to operate in a more democratic and transparent manner.

**May 2007** The results of the consultation on the Pharmaceutical Forum's quality criteria and information package for diabetes reveal flawed methodology and conclusions. Despite this, the High Level Pharmaceutical Forum continues to pursue the public-private partnership approach to 'information to patients'.

**June 2007** The consultation on the *"report on current practices with regard to the provision of information to patients, in particular through the Internet, and on their risks and advantages for the patients"* reaffirms an overall lack of consensus on DTCA and faces the strong criticism of civil society.

**July 2007** A third consultation is launched, this time on *"the future of pharmaceutical products in Europe"*.

**December 2007** The Commission publishes a communication to the European Parliament with a highly incomplete inventory of the sources of medicine and treatment information available for patients, ignoring numerous sources outside of pharmaceutical companies and European regulatory authorities. This partial inventory enables the report to conclude that only the pharmaceutical industry is *"capable of providing patients with the information they so desperately lack"*.

**February-April 2008** A consultation on the EC's proposed legislative changes makes it clear that allowing pharmaceutical companies to communicate directly with consumers about prescription medicines is the Commission's goal.

**October-November 2008** DG Enterprise's proposal is discussed with the other Directorates-General, which results in its release being delayed, suggesting a lack of consensus for the proposal.

**December 2008** The legislative proposal on *Information to Patients* is released by the EU Commission as a component of the Pharmaceutical Package. While covering patient information, it foresees changes to the articles governing advertising of prescription-only medicines in Europe.

**January 2009** The European Federation of Pharmaceutical Industries and Associations (EFPIA) broadly welcomes the recent legislative proposals by the European Commission as a unique opportunity to improve the access of all EU citizens and patients' to high-quality information on health and prescription medicines. Christofer Fjellner (Sweden, EPP-DE) is appointed as the Rapporteur for the Information to Patients proposals.

**February 2009** During a Council working group meeting, health representatives from 25 member states openly oppose the proposals on Information to Patients. Only the Swedish and British representatives support the legislative changes. The Information to Patients proposals remain a contentious item in the discussions.

**March 2009** Discussions continue at EU Parliament level, the Internal Market Committee publishes its draft opinion on the directive and regulation proposals.

**June 2009** The Council of Ministers meets to discuss the proposal and call for caution: "*the distinction between "information" and "advertising" is not sufficiently clear and therefore ... the proposals will not provide sufficient guarantee that the prohibition of advertising of prescription-only medicinal products to the general public will not be circumvented*". A wide range of organisations representing key healthcare stakeholders - patient groups, family and consumer bodies, social security systems, and health professionals – welcome the Council's statements and echo [concerns](#).

**October 2009** The European Committee of the Regions' opinion highlights that the proposed package of legislation is designed to favor the pharmaceutical industry and that the ban on direct-to-consumer (DTC) advertising of prescription medicines should be extended to ads related to campaigns for vaccination and other public health issues.

**November 2009** The portfolio of pharmaceutical products and medical devices is moved from the competence of Directorate-General (DG) Enterprise and Industry to the Health and Consumer-focused DG SANCO in the new European Commission. This policy move is widely acclaimed by the public-health community and independent patient and consumer voices.

**December 2009** MEP Thomas Ulmer from the European People's Party and MEP Carl Schlyter from the European Greens Chair and host an Expert meeting at the European Parliament on the legislative proposals for 'information' to patients. The meeting brings together 93 participants representing a variety of stakeholder groups, including Members of the European Parliament; mainstream and medical press, patient groups, consumer organisations, health insurers, and pharmaceutical industry representatives from industry associations, and individual pharmaceutical companies. [The meeting aimed to raise awareness about the real needs of EU citizens in obtaining reliable, comparative and independent information about medicines; and to highlight how the European Commission's proposals would fall short in meeting such needs.](#)

**January 2010** Recently appointed DG SANCO Commissioner, John Dalli, announces at his first Parliamentary hearing that he will trigger a re-assessment of the legislative proposals to have a clearer distinction between information and advertising. "*We will reassess the package on*

*information and bring more patient perspective to the proposal... You do not want a situation where people in a vulnerable position can be coerced to purchase a product that may not be good for them," he said.*

**March 2010** In a [joint press release](#) 29 organisations question whether the Members of the European Parliament work on such inadequate proposals, as they endanger specific Treaty rules that aim to ensure a high level of health protection.

**September 2010** The European Parliament discusses the proposals. Controversial plans to allow pharmaceutical companies to publish medicines information in newspapers were opposed by MEPs.

**November 2010** The European Parliament adopts its resolutions regarding the Information to Patients proposals and votes on several amendments. The Parliament's first reading is concluded. An amendment to require the pre-approval of materials to be provided by pharmaceutical companies' by competent authorities is adopted, in an attempt to avoid direct-to-consumer advertising.

**December 2010** Taking into account the EU Parliament's opposition, the EU Commission informs the Council at the EPSCO meeting of December 2010 that it will adopt and communicate modified proposals taking into account the amendments voted by the European Parliament.

**January 2011** HAI Europe publishes a study which links sponsorship by pharmaceutical companies with patient and consumer groups policy positions on the Information to Patients [Directive](#).

**October 2011** The EU Commission publishes revised proposals on "information" to patients. The most detrimental provisions (i.e. direct-to-consumer communication via printed media) were removed, taking into account the amendments adopted by the European Parliament. Additional pharmacovigilance provisions were proposed as a consequence of the benfluorex (Mediator) safety scandal in France. HAI Europe, ISDB and the Medicines in Europe Forum warn that the revised proposals contain [loopholes that open the door to advertising of prescription drugs to the public disguised as "patient information"](#). [The rewritten proposals may be misinterpreted and misused.](#)

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<sup>i</sup> Pharmaceutical products: Community code relating to medicinal products for human use, European Commission proposal to the European Parliament, presented 28 June 1999.