

# **Social developments in the European Union 2009**

**Eleventh annual report**

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# EU pharmaceutical policies: direct-to-consumer advertising

Rita Baeten<sup>1</sup>

## Introduction

The clash between the EU's internal market rules and the national competence for healthcare and social protection becomes particularly evident in the field of EU pharmaceutical policies.

Spending on pharmaceuticals accounts for a significant proportion of total health spending in the EU countries<sup>2</sup>. Increased consumption of pharmaceuticals due to the marketing of new drugs and the ageing of populations has been a major factor contributing to increased overall health expenditure (OECD, 2009). Pharmaceutical pricing and reimbursement policies are therefore key elements of national health policies.

Despite healthcare remaining a national-level competence, the evolving EU regulatory framework increasingly impacts on pharmaceutical policies in particular with regard to financing. European legislation ensuring the free movement of pharmaceutical products covers key aspects of pharmaceutical policies. These include market authorisation, data protection, advertising, wholesale distribution and the content of package leaflets. Most of these matters were agreed in the run-up to the 1992 deadline for the Single European Market (SEM). However, with deadlock preventing any further progress in the SEM – particularly over pricing and reimbursement policies – the Commission's focus has shifted towards improving the competitiveness of the industry, the pharmaceutical sector being a key economic sector in the European

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1. I would like to thank Tammy Hervey and Ilaria Passarini for their constructive comments and feedback on earlier drafts of this chapter.
  2. Accounting for between 8 and 27% of health expenditure in the EU Member States (OECD, 2009).

Union (Permanand and Mossialos, 2005). EU pharmaceutical policies have until recently fallen under the responsibility of the European Commission's DG Enterprise, whose task it is to ensure that EU policies contribute to the lasting competitiveness of EU enterprises.

This chapter will highlight these tensions by analysing the recent EU legislative initiatives aiming to relax the prohibition on pharmaceutical companies advertising to the general public pharmaceutical products that are subject to medical prescription.

Direct-to-consumer advertising (DTCA) of prescription drugs is only permitted in New Zealand and the United States. In 2008 the pharmaceutical industry poured \$5 billion into DTCA in the US (Humphreys, 2009). Evidence shows that DTCA is increasing demand for those medicines that are most heavily advertised and is driving sales especially for newer, more expensive drugs for conditions with enormous market potential. It increases demand for drugs that are not necessarily needed, effective or the best value for money. It furthermore prioritises drugs over other treatments and lifestyle changes (see e.g. Law, 2009 and Toop, 2006). The resulting rising costs have also put the issue of drug marketing on the agenda of the current reform of the US health-care system (Humphreys, 2009).

Community legislation prohibits the advertising to the general public of medicines subject to prescription but does allow advertising for other medicines under certain conditions (European Parliament and Council, 2001). The rationale behind this ban is that advertising would boost healthcare expenditure, without necessarily contributing to health gains, and that the needless consumption of drugs can be harmful to health.

A proposal to weaken the EU's ban on advertising prescription-only medicines to the public was overwhelmingly rejected by the European Parliament and the Council in 2003. Despite this, the Commission managed at the end of 2008 to present a new proposal to weaken this ban for direct-to-consumer advertising on prescription-only drugs. The European Commission has been able to keep this issue on the EU policy agenda for more than ten years. In this chapter we will try to understand *how* the Commission has done so and *why*. We will trace the antecedents of the proposal currently under discussion and will

demonstrate that industrial interests rather than health and social concerns have been driving this policy.

Our analysis illustrates the imbalance between the economic and social policy objectives of the EU and reveals a natural alliance between the Commission's single market priorities and the industry's economic demands. Whereas subsidiarity ensures that the Commission has competence over industrial policy matters alone, its institutional leaning is towards the interests of industry (Permanand, 2006).

## **1. Direct-to-consumer advertising on the EU political agenda**

DTCA of drugs has been legal in the United States since 1985, but only really took off after 1997, once the US Food and Drug Administration changed its rules and eased up on a rule obliging companies to offer a detailed list of side-effects in their 'infomercials' (Humphreys, 2009). Ever since then, the pharmaceutical industry has been exerting pressure for DTCA to be allowed in Europe and has managed to put the issue on the policy agenda. Similar discussions about revising the ban on advertising are taking place in Canada and Australia.

The industry's strategies to increase pressure are well illustrated in a 'battle plan' for DTC marketing in Britain and Europe, presented by the Association of the British Pharmaceutical Industry (ABPI) in 2000. It announced: 'to employ ground troops in the form of patient support groups, sympathetic medical opinion and healthcare professionals – known as "stakeholders" – which will lead the debate on the informed patient issue. This will have the effect of weakening political, ideological and professional defences (...). Then the ABPI will follow through with high-level precision strikes on specific regulatory enclaves in both Whitehall and Brussels' (Boessen, 2008).

The issue was put on the policy agenda for the first time during the so-called 'Bangemann' round tables, which were set up by European Commissioner Bangemann at the end of the 1990s to discuss the completion of the Single European Market in pharmaceuticals with Member States and industrial interests. At the final round table in December 1998 DTCA was a central topic, based on a Communication

in which the Commission argued for the issue to be examined in greater depth (Boessen, 2008). The issue was presented in the context of the influence of electronic commerce on advertising (Commission of the European Communities, 1989).

During the same period, the European Commission's DG Enterprise asked the Pharmaceutical Committee – an advisory committee composed of Member States and chaired by the Commission – to set up a working group to review DTC advertising issues. The establishment of such a working group had been requested by the pharmaceutical industry at a meeting of the Transatlantic Business Dialogue in 1998. This forum, composed of major American and European companies, is convened by the US Administration and the European Commission and aims to help establish a Barrier-Free Transatlantic Market<sup>3</sup>. However, since Member States only agreed to provide the working group with an extremely limited mandate, it met just once to circulate a questionnaire (Boessen, 2008).

Two years later, in spite of the clearly limited appetite among Member States, the European Commission presented, in the framework of the so-called 'pharmaceutical review', a legislative proposal to partially lift the ban on DTCA. The proposal allowed manufacturers, in a five-year pilot study, to inform patients about their medicinal products for HIV, AIDS, diabetes and asthma (CEC, 2001). The idea to change the legislation on DTCA was not at any point discussed politically with Member States or Parliament before the proposals were put forward, although the stakes for national healthcare budgets were extremely high. Member States were informed at a special meeting of the Pharmaceutical Committee only days before the review was officially presented to the press (Pharmaceutical Committee and Veterinary Pharmaceutical Committee, 2001; Boessen, 2008).

The plan met with severe criticism in the European Parliament and the Council. The Parliament rejected the proposal at first reading by an overwhelming majority of 494 votes against, 42 in favour and 7 abstentions, and this notwithstanding the fact that the rapporteur on

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3. [http://www.tabd.com/index.php?option=com\\_content&task=view&id=16&Itemid=45](http://www.tabd.com/index.php?option=com_content&task=view&id=16&Itemid=45)  
(accessed on 6 January 2010).

the issue, Françoise Grossetête, was much less critical of the Commission proposal (European Parliament, 2002).

The European Parliament did nevertheless ask the Commission to present a report outlining a comprehensive consumer/patient information strategy to ensure good quality, objective, reliable and non-promotional information on medicinal products and other treatments, based on an amendment laid down by Rapporteur Grossetête (European Parliament, 2002). There are reliable indications that this amendment was drafted in close consultation with the Commission's DG Enterprise, once it became clear that the Parliament would veto the proposed pilot (see e.g. Boessen, 2008).

In spite of this overwhelming rejection, the European Commission, in its revised proposal, did not accept the parliamentary amendment deleting the pilot project with regard to information on prescription-only drugs (CEC, 2003a), even though it was already very clear at that stage that the Member States in the Council did not want to accept this aspect of the pharmaceutical review either. And indeed, in its common position adopted a few months later, the Council did not accept the Commission's proposal to relax the ban on pharmaceutical advertising (Council of the European Union, 2003b).

In December 2003 the European Parliament and the Council scrapped the pilot project, whilst retaining the request to the Commission to provide a report on patient information<sup>4</sup>. This request for a report allowed the Commission to keep the issue on the agenda (Boessen, 2008).

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4. The full wording of this amendment, Article 88a of Directive 2001/83/EC, introduced by Directive 2004/27/EC states: 'Within three years of entry into force of Directive 2004/27/EC, the Commission shall, following consultation with patients' and consumers' organizations, Member States and other interested parties, present to the European Parliament and the Council a report on current practice with regard to information provision – particularly on the Internet – and its risks and benefits for patients. Following analysis of the above data, the Commission shall, if appropriate, put forward proposals setting out an information strategy to ensure good-quality, objective, reliable and non-promotional information on medicinal products and other treatments and shall address the question of the information source's liability'.

The European Commission did not give up the battle, however. Already in 2001, in parallel to the discussions on the pharmaceutical review, the Commission had set up a G10 High Level Group on innovation and the provision of medicines. It was composed of representatives of some Member States, some pharmaceutical companies, health insurers and a research centre on patients' views, all selected by the European Commission itself, which chaired the Group. The pharmaceutical industry was overrepresented compared to health advocacy groups<sup>5</sup>. It aimed 'to establish common ground and agree objectives on a new agenda to improve the framework for competitiveness in the pharmaceutical industry and to harness its power to deliver on Europe's healthcare goals'. Information to patients was one of areas on the agenda of the G10. It was perceived as an initiative to build consensus on ideas for which the Commission did not get enough backing in the legislative process of the pharmaceutical review. It was a safety net to keep issues that were not agreed upon in the review on the political agenda (Boessen, 2008). With regard to information to patients, the G10 recommended in its final report the production, in cooperation with all stakeholders, of a workable distinction between advertising and information; the development of standards to ensure the quality of such information; and the establishment of a collaborative public-private partnership involving a range of interested parties (CEC, 2002). In its reply, the European Commission announced its intention to explore, with stakeholders, a range of approaches to provide 'a realistic and practical framework for the provision of information on prescription and non-prescription medicines' (CEC, 2003b). The European Commission thus successfully used the informal G10 debates to bypass the traditional institutions involved in the Pharma Review (Hervey and Vanhercke, 2010). Or, in the words of the European Commissioner: 'The G10 Medicines process has been valuable in reaching consensus in areas where there has often been sterile debate. Our task now is to work with Member States and the European Parliament to ensure that the process has a long-term beneficial impact' (CEC, 2003c).

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5. From the Member States, the Swedish Minister of Industry, together with the French, German, UK and Portuguese Ministers of Health; from the industry, EFPIA, EGA, AESGP; from health insurers, AIM; and for patients the Picker Institute.

Further to this Commission Communication, the Council of the European Union adopted a resolution on 'Pharmaceuticals and public health challenges – focusing on the patients', in which it invited the Commission to explore together with Member States the possibility of setting up a European Information System for patients and health professionals (Council of the European Union, 2003).

In spite of the fact that its legislative proposal for a pilot project to partially lift the ban on advertising for prescription-only drugs had been rejected by the European Parliament and the Council by overwhelming majorities, the Commission thus had a request in early 2004 to study information provision and, if necessary, propose new legislation (review result); a recommendation to establish a public-private partnership (G10) and a mandate to explore options for a European information system (Council resolution) (Boessen, 2008).

To take the process further and tackle some of the recommendations of the G10, the European Commission set up the High Level Pharmaceutical Forum in 2005, as a three-year process. The Forum brought together Ministers from – this time – all the EU Member States, Members of the European Parliament and representatives of the pharmaceutical industry, healthcare professionals, patients and insurance funds. It was chaired by the European Commissioners responsible for public health and for industry.

Information to patients on pharmaceuticals was the theme of one of the three expert working groups of the Forum. This working group agreed on a set of quality principles on information to patients and on key elements for core information<sup>6</sup>. These had been submitted to a public consultation<sup>7</sup>.

However, the European Social Insurance Partners (ESIP) and the Association Internationale de la Mutualité (AIM), the European umbrella organisations of social health insurers, dissociated themselves from the work of this working group and expressed strong concerns

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6. [http://ec.europa.eu/pharmaforum/docs/itp\\_quality\\_en.pdf](http://ec.europa.eu/pharmaforum/docs/itp_quality_en.pdf) (accessed on 7 January 2010).

7. [http://ec.europa.eu/enterprise/phabiocom/comp\\_pf\\_consult\\_2007\\_2.htm](http://ec.europa.eu/enterprise/phabiocom/comp_pf_consult_2007_2.htm) (accessed on 11 February 2010).

about the lack of transparency in the Forum, particularly in the above-mentioned working group. They criticised the working group for not taking into consideration the suggestions they put forward in the process and debate (ESIP and AIM, 2007). They also criticised the Forum for being ‘dominated by market-driven interests to the detriment of public health interests’ (AIM and ESIP, 2008). These views were endorsed by a coalition of organisations of mutual insurers, patients, prescribing health professionals, independent drug bulletins and public interest organisations (Medicines in Europe Forum, ISDB, HAI Europe, 2007). They argued that information to patients should not come directly from those who produce medicines because the main goal of pharmaceutical companies is to maximise sales. They expressed concern over the conflicts of interest if pharmaceutical companies are allowed to provide information for patients.

Given the composition of the Forum, with strongly opposed interests and objectives of the participating stakeholders, its final conclusions, which were presented in October 2008, remained rather general and did not provide the clear mandate the European Commission was hoping for. With regard to access to and quality of information to patients on diseases and treatments, the Forum argued for greater accessibility of information to citizens and suggested new collaborations between public and private partners in the field of information to patients. It recommended that ‘all the relevant players, including national competent authorities, the Commission, public health stakeholders and industry, should ensure high quality information and thereafter should commit themselves to implementing and using the core quality principles and their methodology of use for the development of information, and to identifying poor quality information’. The European Commission was invited to set up a process to evaluate the direct outcomes and follow-up of the Pharmaceutical Forum on information to patients (High Level Pharmaceutical Forum, 2008). A footnote specifies that AIM, the umbrella organisation of the social mutual insurance funds, ‘expressed some reserves concerning the involvement of industry in providing information to patients’.

Without however awaiting the final conclusions of the Pharma Forum and without liaising with this Forum, the European Commission organised in parallel in 2007 a consultation on current practices with regard to the provision of information to patients on medicinal products

(CEC, 2007a). This consultation was a sole initiative of DG Enterprise, unlike the Pharmaceutical Forum which was led by both DG Enterprise and DG Sanco (health and consumer protection). It looks as though DG Enterprise, aware of the deadlock in the Pharma Forum, wanted to open up an alternative avenue to achieve legitimation to continue its efforts to allow the pharmaceutical industry to provide information on its medicines to patients. When the Commission put forward its legislative proposal at the end of 2008, it did indeed justify its initiative on the grounds that ‘The responses to the public consultation confirmed that the legislative framework on information to the patients should be improved’ (CEC, 2008g). DG Sanco was much more reluctant to go ahead with a legislative proposal. The report on ‘current practices with regard to the provision of information to patients on medicinal products’ was presented as the implementation of the mandate the Commission received in the 2004 pharmaceutical review under Article 88a of Directive 2001/83/EC, mentioned above. However, the Commission report is limited to ‘provision of information to patients on medicinal products’ whereas Article 88a requests a report on ‘information on medicinal products *and other treatments*’ (CEC, 2007b). This strengthens the assumption that the mandate inserted during the 2004 pharmaceutical review was intended to enable the Commission to work on the issue, but was formulated in a way that made it difficult for MEPs to oppose, since its formulation suggested patient empowerment objectives.

Public health stakeholders heavily criticised the Commission report, stating that ‘the report’s conclusions are exclusively biased in favour of allowing drug companies to communicate directly with the public, further undermining the Commission’s credibility’, and ‘Despite the incomplete inventory of sources of information in Europe in this report, and the flawed methodology used to produce it, the authors come to the firm conclusion that only the pharmaceutical industry is capable of providing patients with the information they would otherwise miss’ (ISDB *et al.*, 2007).

## **2. The pharma package: second attempt to regulate DTCA**

In December 2008 the European Commission yet again put forward a legislative proposal to allow pharmaceutical companies to provide certain types of information to patients. This proposal was presented as part of the so-called 'pharmaceutical package', a raft of texts on pharmaceutical legislation, consisting of four key parts:

- 1) A Communication to launch reflection on ways to improve market access and price-setting mechanisms and to develop initiatives to boost EU pharmaceutical research (CEC, 2008a);
- 2) A proposal to tackle counterfeiting and illegal distribution of medicines (CEC, 2008b);
- 3) Proposals to strengthen the EU system for the safety monitoring ('pharmacovigilance') of medicines (CEC, 2008e);
- 4) Proposals to allow pharmaceutical companies to provide information on prescription-only medicines to patients (CEC, 2008c and 2008d).

The presentation of the proposal to relax the ban on advertising was preceded, in early 2008, by yet another public consultation organised by the European Commission's DG Enterprise, on a document containing the key principles for a legislative proposal (CEC, 2008f). But this consultation too was launched before the Pharmaceutical Forum had presented its final conclusions, and did not refer to or take into account the work of this Forum. The document argues that any communication not covered by the definition of an advertisement should be regarded as information, and aims to clarify the distinction between allowed and non-allowed information.

In a reply, the Council called on the Commission in May 2008 to provide a clear definition of non-promotional information, instead of a definition of advertising as suggested by the Commission. The Council stressed the need for in-depth reflection on the issue with a view to a more rational use of medicines and to avoiding unnecessary administrative burdens for competent authorities and marketing authorisation holders (Council of the European Union, 2008).

We may well wonder why, for its legislative proposals, the Commission did not build on the work of the Pharmaceutical Forum. Carboni points out that ‘the Pharma Package was the result of strong lobbying, especially from industries’ (Carboni, 2009). She suggests that the Commission might have used soft instruments such as consultation platforms to divert the attention of public interest advocacy groups away from the process of drafting the legal proposal (Carboni, 2009). The fact that even the website of DG Enterprise suggests that it would take a non-legislative approach to addressing the issue of information to patients is an element that validates this assumption<sup>8</sup>. Carboni cites a lobbyist of a health organisation: ‘It was very bad. The Commission was preparing the package while we were engaged in the Pharma Forum. Therefore, it was not very clear who contributed to it. Only one result of the Pharma Forum – the quality criteria – was partially included in the package’. Commission policy officials involved in the process argued that the Pharma Forum and the Pharma Package were not linked to each other, and the Pharma Forum was not used to discuss the upcoming Commission legislative proposals, because ‘the Pharma Forum and the Pharma Package were moved by different political mandates. The Commission is a very fragmented policy house: each DG has its own political mandate and communication is not very easy among different Units’ (Carboni, 2009). The two DGs involved in the policy-making process – DG Enterprise and DG Sanco – thus had their own policy agendas.

The adoption of the pharmaceutical package by the EU executive had been delayed several times and had been the subject of tricky negotiations within the Commission. With regard to the proposal on information to patients, disagreements arose essentially between Commissioner Vassiliou, responsible for Health, and Commissioner Verheugen (Enterprise). As a result, several important provisions were modified, amongst other things to refer the question of distributing information via the printed press back to the Member States<sup>9</sup>.

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8. [http://ec.europa.eu/enterprise/sectors/pharmaceuticals/competitiveness/information-to-patient/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/pharmaceuticals/competitiveness/information-to-patient/index_en.htm), accessed on 11 February 2010.

9. *Bulletin of the European Union*, No.9800, 10 December 2008.

The legislative proposal on information on prescription-only medicines includes the following provisions (CEC, 2008c and 2008d):

Certain types of information are exempted from the scope of the provisions prohibiting advertising of prescription-only medicines: (1) Summaries of products characteristics, labelling and package leaflets, as approved by the competent authorities or information which does not go beyond these elements, but presents them in a different way; (2) Information on prices and factual, informative announcements; (3) Product-related information about non-interventional scientific studies, or accompanying measures to prevention and medical treatment or information which presents the medicinal product in the context of the condition to be prevented or treated.

Communication channels for the dissemination of information that are allowed according to the proposal are (1) internet websites on medicinal products, to the exclusion of unsolicited material actively distributed to the general public; (2) written answers to a request for information of a member of the general public; (3) in the printed press, in health-related publications as defined by the Member State of publication, to the exclusion of unsolicited material actively distributed to the general public. Information on TV and radio are excluded.

The information provided must comply with certain quality criteria such as being objective and unbiased; being based on evidence and verifiable; up-to-date; reliable; factually correct and not misleading; understandable and not contradict the product information as approved by the competent authorities.

Member States are expected to monitor the information made available. In general, the information should be subject to monitoring after it has been disseminated. Some types of information are however subject to *ex ante* instead of *post hoc* monitoring. Internet sites containing information on prescription-only medicinal products shall be registered and monitored.

If we compare the final proposal with the document submitted for public consultation by DG Enterprise (CEC, 2008f), some provisions have been restricted. The possibility to provide information in the audiovisual media was removed. According to the Health Commissioner, this was done at her insistence<sup>10</sup>. However, the umbrella organisation of the pharmaceutical industry, EFPIA, already stated in its reply to the public consultation on the draft proposal that it considers neither TV and radio nor the print mass media to be appropriate ways for the industry to communicate information on specific prescription medicines to European citizens (EFPIA, 2008). This does not mean that EFPIA is opposed to allowing the industry to advertise in these media, but they propose that this should only be 'general information on diseases, e.g. covering awareness, prevention etc. but not mentioning specific medicines'. Information on the specific medicines would then be provided in 'specialised' media or at the request of the patient. This position might well be part of a charm offensive, given the assertions from within the industry itself that recourse to direct-to-consumer ads was 'the single worst decision' drug makers had ever made, because of the damage it had done to their image (Humphreys, 2009). It might well also be more advantageous from a marketing viewpoint to raise awareness in the general audiovisual media only about disorders for which it is the intention to promote medicines, without clarity about who is providing the seemingly objective 'information' and without mentioning the specific medicine, thus encouraging patients to look themselves for information on the pharmaceutical products.

Furthermore, according to the final proposal some types of information are subject to *ex ante* instead of *post hoc* monitoring. However, the text still contains inconsistencies in this respect. Member States are also given more freedom to determine the mechanism for monitoring the information. The idea of obliging Member States to establish co-regulatory bodies in a public-private partnership to supervise the information providers and to establish national codes of conduct, as initially proposed by DG Enterprise, was not maintained.

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10. Intervention by Commissioner Vassiliou at the conference 'Health systems governance in Europe, the role of EU law and policy', on 11 December 2008 in Brussels.

### 3. The policy process and stakeholder positions

The Council reacted particularly strongly against the Commission proposal. At the Council of June 2009, over 20 Member States did not see the proposal as ‘an appropriate basis for continued negotiations’ (Council of the European Union, 2009b). They maintain that the distinction between ‘information’ and ‘advertising’ is not sufficiently clear and therefore fear that the proposals will not provide sufficient guarantees that the prohibition of advertising of prescription-only medicinal products to the general public will not be circumvented (Council of the European Union, 2009c). They fear that the suggested system will be overly burdensome for competent authorities without leading to significant improvements in the quality of the information provided to patients. Some Member States held that the proposal, if adopted as it stood, may have significant negative consequences on healthcare budgets owing to a possible unjustified increase in the use of medicinal products (Council of the European Union, 2009b). As a result, the Czech and Swedish EU presidencies left the proposal untouched.

European Commissioner Günter Verheugen, who throughout his term of office was personally very committed to making this change of legislation happen, initially did not want to cede to the Council rejection of the Commission’s proposal<sup>11</sup>. In September 2009 he declared before the European Parliament that he was ‘more than ever convinced’ of the merits of the proposal and rejected the position of Member States in strong terms, regretting that health bureaucracy was almost impossible to combat<sup>12</sup>. Nevertheless, only three months later, at the Health Council in December 2009, the Commission made clear that it was prepared to show flexibility in order to find a common basis for future negotiations (Council of the European Union, 2009b). It might well be that negotiations between the Commission’s DG Enterprise and the pharmaceutical industry in the meantime led to this changed position. Indeed, Arthur Higgins, president of EFPIA, declared at a press conference in November 2009 that the industry would allow an

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11. *Europolitics*, 10 June 2009.

12. *Bulletin of the European Union*, No.9967, 2 September 2009.

independent authority to vet information provided to patients<sup>13</sup>. This is considered as a concession from the pharmaceutical industry<sup>14</sup>.

Strikingly, the press conference at which the industry revealed its changed position was organised in the European Parliament, jointly with Françoise Grossetête, the French EPP MEP who has since 2000 been EP rapporteur for many key legislative acts on pharmaceutical products, including the pharmaceutical review (see above) and who represented the European Parliament in the Pharmaceutical Forum. At this press conference she called on MEPs to join with patient groups to form a united front against health ministers who have blocked the directive<sup>15</sup>. This again smacks of strong collusion between the pharmaceutical industry, some MEPs in key positions and the European Commission.

The new Commission is expected to come up with amendments to the current proposal<sup>16</sup>. The Health Commissioner designate, John Dalli, called during his hearing at the European Parliament for progress to be made on the issues where consensus can easily be built (pharmacovigilance and counterfeit products) and to leave the most divisive issues to be tackled separately<sup>17</sup>.

The votes on the proposal in the European Parliament are expected in the competent committee and the plenary session in June 2010. The rapporteur on the proposal, Christofer Fjellner (EPP, Sweden), is known to be 'positive' about the Commission's proposal and wants to find a backing majority in the EP<sup>18</sup>. Other Christian Democrats are however less supportive of the proposal and are calling for genuinely

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13. <http://www.euractiv.com/en/health/pharma-industry-softens-stance-advertising-plan/article-187005>, accessed on 11 February 2010.

14. The industry is however well aware of the fact that health authorities are unable to validate all the information and that prior vetting is even forbidden by some Member States' constitutions.

15. <http://www.euractiv.com/en/health/pharma-industry-softens-stance-advertising-plan/article-187005> accessed on 11 February 2010.

16. *Europolitics*, 2 December 2009.

17. <http://www.euractiv.com/en/priorities/dalli-guardian-consumers-interests/article-188912>, accessed on 15 January 2010

18. See e.g. <http://www.fjellner.eu/fjellners-anforande-om-patientinformation>, accessed on 12 January 2010.

objective information<sup>19</sup>. On the whole, the positions of the MEPs seem not to be along to the lines of the political groups. Other factors, such as the importance of the domestic pharmaceutical industry<sup>20</sup>, or the political agendas of the stakeholder groups behind the MEPs<sup>21</sup>, also seem to play a role.

So far, it looks as though there is less vocal criticism of the proposal in the European Parliament than in the Council.

The rapporteur on this issue in the Committee of the Regions, Susanna Haby (SE/EPP), warned in a press release that the EC pharmaceutical proposals put patients at risk and are biased in favour of pharmaceutical companies (Committee of the Regions, 2009). It is worth noting that she is from the same country and political party as the rapporteur in the European Parliament, who takes a completely opposite view.

The European Economic and Social Committee, the consultative body representing the European social partners, is also quite critical of the proposal. It states that it is difficult to distinguish between advertising and information, and recommends setting up an independent body to provide information. It urges that information on non-interventional scientific studies should not be considered as information which can be disseminated to the public and that 'health-related publications' are not an appropriate means of disseminating information on prescription-only medicines (European Economic and Social Committee, 2009).

Before the Pharma Package was unveiled, twenty umbrella organisations in the field of health, representing patients, consumers, health professionals and social health insurers sent a joint letter to both Health Commissioner Vassiliou and the President of the EU Commission,

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19. German Christian Democrat Peter Liese and Belgian Christian Democrat Anne Delvaux, 02/09/2009 (Bulletin of the European Union, 2009).

20. For instance, the German Socialist MEP Dagmar Roth-Behrendt said she could not understand the aversion to providing controlled information to patients. <http://www.euractiv.com/en/health/commissioner-final-plea-drug-information-directive/article-185025> retrieved on 12 January 2010, whereas many other social democrats expressed strong concerns about the proposal (<http://www.eph.org/a/3313>).

21. For instance, Christofer Fjellner is a former researcher at the Swedish free market hardliner think tank Timbro, which later formed the Stockholm Network.

Mr Barroso, to express their fears about the draft proposal relating the pharmaceutical package, in particular the role it would give to the pharmaceutical industry concerning information to patients on prescription-only medicines (Age *et al.*, 2008a and 2008b).

Most of these stakeholders also welcomed the Health Ministers' critical conclusions on the proposed directive, stating that 'Under the guise of patient "information", these proposals would, in reality, lead to the relaxation of the ban on direct-to-consumer advertising of prescription medicines in Europe, risking citizens' safety and the sustainability of national healthcare systems' (Age *et al.*, 2009).

#### **4. Discussion**

Having learned from its initial failure in legislating on the topic during the pharmaceutical review in 2001-2004, the European Commission involved stakeholders and tried build consensus through the creation of high-level reflection groups and all kinds of public consultations. By organising a multitude of parallel initiatives the Commission created a whole series of avenues from which it could draw legitimation for further actions at the appropriate moment. The Commission thus managed to keep the issue on the agenda and to bypass formal legislative veto points by using informal avenues or practices (Carboni, 2009).

By taking parallel and overlapping initiatives, the Commission created confusion, which diverted stakeholders' attention. By those means, the Commission could remain the sole player in control of the whole process. The non-transparent approach of inviting stakeholders often resulted in an overrepresentation of industrial interests. Also, the formulation of the consultation papers was geared towards a role for industry, and the conclusions of the consultations did not reflect in a balanced way the replies of the different stakeholder groups (Boessen, 2008).

The Commission played the role of policy broker. By favouring an exchange of information and opinions among stakeholders, building supportive networks and promoting public consultations, the Commission tried to influence the policy outcome of its proposals (Carboni, 2009).

The public consultations, furthermore, were instrumental in depoliticising the debates and aimed to create ownership of the final proposals among stakeholders (Hervey and Vanhercke, 2010).

Throughout the policy process, the European Commission's DG Industry was in close contact with the pharmaceutical industry. It is striking that Commissioner Verheugen twice gave way on its position on the legislative proposal, each time after a public declaration by EFPIA proposing a change in the draft. This was the case with the changes made during the adoption of the proposal by the College of Commissioners and with Mr Verheugen's declaration in the Council of December 2009 that he was prepared to show flexibility.

This is in line with the findings of Permanand, based on an analysis of other EU initiatives in the field of pharmaceutical legislation. He shows that the research-based industry was present at every stage of the policy process: the policy networks invariably began with the Commission and EFPIA (Permanand, 2006). DG Enterprise, responsible for the draft legislation, selectively offered access to advocacy groups whose policy preferences were in line with those of the DG (Boessen, 2008 and Carboni, 2009). DG Enterprise gave access and listened to pharmaceutical companies and associations, more than it did to public health and consumer groups. Carboni even quotes a policy officer at DG Enterprise stating '*We represent industries*' (Carboni, 2009). Whereas industry and some patient groups had good access to DG Enterprise, the point of reference for public health and consumer organisations was DG Sanco. Abraham shows how the pharmaceutical industry managed, at the national level too, to influence drug regulation by persuading governments and their regulatory agencies that other interested parties, such as consumer organisations, patients' associations and the wider medical and scientific community, should have few or no rights of access to the regulatory process (Abraham, 2002).

Throughout the whole process, DG Enterprise overruled DG Sanco. DG Sanco was known to be against the initial 2001 proposal for a pilot study (Boessen, 2008). Also, during the Pharmaceutical Forum the relationship between the two Commissioners of DG Enterprise and DG Health (Günter Verheugen and Markos Kyprianou respectively) co-chairing the Forum seemed rather tense. They had different views with regard to the legislative proposal. DG Sanco was however unable to

counterbalance the industry-oriented proposals of DG Enterprise (Carboni, 2009).

Rhetoric was important. The Commission cleverly reframed the issue in many ways and created confusion about the concepts. The rhetoric was in line with the approach taken by the research-based industry.

The issue was presented from the onset in the context of improving the competitive position of the European pharmaceutical sector *vis-à-vis* US industry. It was argued that Europe as a whole is lagging behind in its ability to generate, organise and sustain innovation (see e.g. CEC 2002 and 2008a). This discourse is the same as the discourse of EFPIA, the association of the European-based pharmaceutical industry, which states that, since the early 1990s, the research-based pharmaceutical industry in Europe has been losing competitiveness with respect to its main competitors, in particular the US<sup>22</sup>. Yet a recent comprehensive study shows that the United States never did overtake Europe in research productivity, and that Europe in fact is pulling ahead of US productivity (Light, 2009). As shown by Abraham, this type of argument has constantly and successfully been used by the pharmaceutical industry for the last 50 years to ward off regulation it perceives to be contrary to its interests, not only at EU level but also at national level. He argues that the pharmaceutical industry has been quick to warn that such regulation results in research going abroad or damages results for the nation's export trade, balance of payments or employment. He provides evidence showing the opposite of what the industry has been claiming (Abraham, 2002).

The Commission presented its proposals as proposals on information to patients rather than advertising. In this way it hoped to find allies in the European Parliament and among patient advocacy groups in favour of patient empowerment. Since actors could not simply ignore a request for information, this concept allowed the discussions to continue (Boessen, 2008). However, a clear definition of non-promotional information was never put forward. This resulted in more confusion rather than more clarity on the difference between information and advertising. Moreover, confusion was created between information on

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22. <http://www.efpia.eu/content/default.asp?PageID=388>, accessed on 19 January 2010.

pharmaceutical products on the one hand and information on diseases and treatment options on the other, which allowed for the use of the mandates received from the European Parliament and the Council during the pharmaceutical review.

The notion of ‘equal access’, which primarily has a social connotation and which it is thus difficult to oppose, was used to refer to the differences in national legislation on the kind of information the pharmaceutical industry is allowed to provide to patients.

The term ‘independence’ (freedom from commercial influence) was replaced by ‘objective’. However, objective information can also be misleading owing to incompleteness or a lack of balance and context (Toop and Mangin, 2007).

Unlike the 2001 pharmaceutical review proposal, in the 2008 Pharma Package the different policy topics - the reform of pharmacovigilance, the legislation on counterfeits and the DTCA – are presented in different legal acts. This allows progress to be made on the less controversial proposals, whilst delaying the policy process on DTCA. During the pharmaceutical review it was in fact argued that the whole reform should be approved before enlargement, which did not allow for complex compromise building on the topic of information to patients (Boessen, 2008).

However, the Commission seems not really to have succeeded in making stakeholders change their views. The issue has remained extremely controversial, as illustrated by the strong reactions from the Council and health advocacy groups. Carboni argues that policy learning as a process is most likely to concern only secondary aspects of a belief system, leaving the policy core of a coalition intact, and bringing only minor policy changes (Carboni, 2009).

So far, it appears that there are less critical noises and more goodwill towards the legislative proposal in the European Parliament than there were during the pharmaceutical review of 2002. The composition of the European Parliament is different, and EU enlargement brought new perspectives into the Parliament. The European Commission’s efforts to strike the right note of the debate and to reframe the issue of DTCA might well have had their desired effect on MEPs. The strong terms in which Commissioner Verheugen, speaking in the European Parliament,

and MEP Françoise Grossetête, condemned Member States' rejection of the proposal is also part of the strategy. MEPs are susceptible to arguments allowing them to take a stance asserting the Parliament's position in relation to the Council.

Direct lobbying of MEPs by the pharmaceutical industry certainly also plays a role. MEPs are more dependent than Commissioners or Member States on lobby groups to provide them with vital information and expertise to form their opinion, since they have limited resources to analyse all the aspects of the legislative proposals submitted to the Parliament (Carboni, 2009). Especially regarding proposals for which there is no clear guidance from the political groups, as is the case with this issue, MEPs are more vulnerable to lobbying by interest groups. The pharmaceutical industry has much greater financial and human resources to come to MEPs' aid than health advocacy groups. But at this stage of the decision-making process it is even more important to have preferential contacts with some specific MEPs, considered as opinion leaders on the topic, or to be able to influence the appointment of MEPs to key positions. The joint press conference of the pharmaceutical industry with Françoise Grossetête, the MEP who has since 2000 been rapporteur in the EP for many important legislative acts on pharmaceutical products, including the pharmaceutical review (see above), is enlightening in this respect. The appointment of Christofer Fjellner, who has a track record in hardline free-market organisations, as rapporteur on the proposals, might also have its importance.

## **5. The Lisbon Treaty: towards a new balance?**

Almost unnoticed, the Lisbon Treaty inserted a new legal basis in the Treaty on the Functioning of the European Union for EU pharmaceutical legislation.

The new Art. 168, on public health (former Art. 152), states:

(...)

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure

and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

- (a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;
- (b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;
- (c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

As a consequence, future EU harmonising measures in the field of pharmaceutical products (and medical devices) will in principle be based on Article 168 TFEU, rather than on the articles on the internal market as has been the case so far. Furthermore, with the inauguration of the new European Commission, the Commission services responsible for pharmaceutical policies will be transferred from DG Enterprise to DG Sanco.

It is too early to tell what the policy effect thereof might be. Health advocacy groups have long argued for this transfer (EPHA *et al.*, 2009). It will in principle imply that the stakeholder coalitions defending industrial interests and public health respectively will meet with officials of the same service within the Commission, whereas so far each of them had access to a different DG. However, one might wonder whether this will really impact on the Commission's views. For instance, the fact that, in the last few years, pharmaceutical policies have increasingly been discussed in the Council formation responsible for health, whereas before they were discussed in the Council responsible for economic policies, has not really changed the Commission's positions, although both responsible DGs, Enterprise and Sanco, were represented at the meetings. The EU still has no responsibility for healthcare organisation, delivery and especially funding. Furthermore, industry lobbies remain extremely powerful.

Nevertheless, the changed Treaty provision might bring about a shift in the dominant paradigm on EU pharmaceutical policies. DG Sanco's task

is to protect human health rather than to ensure that EU policies contribute to the lasting competitiveness of EU enterprises. This might lead at least to a different rhetoric.

## **Conclusion**

This chapter has illustrated, based on a concrete policy proposal, the clash between the EU's free movement rules and the national competence for healthcare policy.

The European Commission managed to keep the issue of relaxing the ban on direct-to-consumer advertising on the policy agenda for more than ten years. The Commission had a clear agenda: to allow pharmaceutical companies to communicate directly with patients on prescription-only drugs. This topic emerged under pressure from the pharmaceutical industry, in the wake of the relaxation of the rules on DTCA in the US. Throughout the policy process, the competent DG, DG Enterprise of the European Commission, remained in close contact with the pharmaceutical industry.

The Commission managed to keep the issue on the agenda thanks to a succession of initiatives through which it could receive mandates to continue working on the topic. Having learned from its initial failure in legislating on the DTCA during the pharmaceutical review of 2001-2004, the European Commission tried to build consensus through the creation of high-level reflection groups involving stakeholders.

By taking parallel and overlapping initiatives such as consultations, the Commission created confusion and could remain the sole player in control of the whole process. The way in which stakeholders invited to participate in the processes were selected, consultation papers were formulated and conclusions were interpreted, were biased and geared towards a role for industry in information provision.

Rhetoric was important. The Commission reframed the issue in many ways and created confusion about the concepts.

The Commission did not really succeed in making the stakeholders change their views, however. The issue remained extremely controversial

for Member States and health advocacy groups. The Commission's initiatives might nonetheless have created more good will towards the legislative proposal in the European Parliament, although it is too early to have a complete insight into Parliament's position.

We can assume that, as long as the EU has no financial responsibility over healthcare provision, other policy objectives that are more in line with the EU's core business, namely the creation of the internal market, will gain the upper hand in its policy initiatives. Nevertheless, the insertion of a new legal basis on pharmaceutical legislation into the public health article in the Treaty of Lisbon might lead to a different paradigm, at least at the level of rhetoric. In addition, the fact that the same Commission services will be in contact with all the relevant stakeholders might also encourage a more balanced approach in the EU's pharmaceutical policies.

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