

Divide & Conquer:

A look behind the scenes of the
EU pharmaceutical industry lobby



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Divide & Conquer:

A look behind the scenes of the European Union (EU) pharmaceutical industry lobby

Correspondence addresses: katrina@haieurope.org & olivier@corporateeurope.org

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Health Action International (HAI) Europe

Overtoom 60 II, 1054 HK Amsterdam. Netherlands. Tel: +31 20 683 3684 Fax: +31 20 685 5002.

Health Action International (HAI) is an independent, European network working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy.

www.haieurope.org

Corporate Europe Observatory (CEO)

Rue d'Edimbourg 26, 1050 Brussels. Belgium. Tel: +32 (0)2 893 0930

Corporate Europe Observatory (CEO) is a research and campaign group working to expose and challenge the privileged access and influence enjoyed by corporations and their lobby groups in EU policy making.

<http://www.corporateeurope.org>

The information presented here was retrieved from online sources including the EU Transparency Register between 15-31 January 2012, unless otherwise indicated.

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Abbreviations

ALTER-EU	Alliance for Lobbying Transparency and Ethics Regulation
ABPI	Association of British Pharmaceutical Industries
CEO	Corporate Europe Observatory
COPD	Chronic obstructive pulmonary disease
DG SANCO	Directorate General for Health and Consumer Affairs
EABC	European-American Business Council
ECC	European COPD Coalition
EUCOPE	European Confederation of Pharmaceutical Entrepreneurs
EFPIA	European Federation of Pharmaceutical Industries and Associations
EPHA	European Public Health Alliance
GIG	Genetic Interest Group
GSK	GlaxoSmithKline
HAI Europe	Health Action International Europe
IPRs	Intellectual property rights
MEP	Member of the European Parliament
MiEF	Medicines in Europe Forum
NHS	National Health System
PhRMA	Pharmaceutical Research and Manufacturers of America
PPTA	Plasma Protein Therapeutics Association
TACD	Trans-Atlantic Consumer Dialogue

Executive Summary

This report surveyed the entries made by pharmaceutical companies and their representatives in the EU's lobby Transparency Register to find out how much the industry claimed to spend on lobbying. According to these findings, the pharmaceutical industry lobby is spending more than €40 million annually to influence decision making in the European Union (EU) – of which nearly half is spent by drug manufacturers on in-house lobbyists.¹

Results from this study show that many pharmaceutical companies lobbying the European Commission on legislation fail to declare their activities to the Register. As registration to the Transparency Register is voluntary, many pharmaceutical companies choose not to declare their expenditures. If recorded properly, expenditure on lobbying activities by the industry could be shown to be as high as €91 million annually.²

Civil society organisations active on EU medicines issues, on the other hand, spend a combined €3.4 million per year. With the immense disparity between the affluence of public interest groups and the industrial lobby, it becomes even more difficult to level the policy playing field.

This estimate is more comparable to pharma's lobby footprint in the USA, where the pharmaceutical manufacturing sector has reportedly spent about €85.5 million (\$115 million USD) in lobbying the American government in 2011. The report estimates that 220 lobbyists are active in the EU on behalf of the pharmaceutical industry, which pales in comparison to nearly 1500 industry lobbyists documented in the US in 2011. Clear and enforced reporting rules in the US yield a more accurate picture of pharma's lobby contingent in America as compared to the EU.

This report also reveals a number of persistent shortcomings in the EU Transparency Register:

- **Organisations engaged in lobbying fail to sign-up to the register.** At least six pharmaceutical companies engaged with DG SANCO in 2011 but do not maintain an entry in the Transparency Register. Neither do an additional six companies who hired various lobby firms to represent their interests to the EU. These 12 companies represent half of those companies who have entries in the lobby register.

¹ This figure is valid on 31 January 2012. It does not reflect subsequent changes to the EU Transparency Register.

² This figure is valid on 31 January 2012. It does not reflect subsequent changes as the EU Transparency Register.

- **Under-reporting still plagues entries in the register.** EFPIA, Europe's largest pharmaceutical industry association, reported an investment of 50,000 Euro in EU interest representation in 2010, despite claiming to employ ten staff members whose work falls under the scope of the Transparency Register.³ Declared lobby spending that is insufficient to support the reported number of staff could be a sign of underreporting.
- **The financial information in the lobby register is far from precise.** Consultancies, companies and trade or professional associations can choose to report their lobby spending in ranges of €50,000, € 100,000 or €250,000, depending on their total lobbying turnover. Moreover, consultancies need only report income from each client in similar ranges of different size depending on the size of the contract.
- **Recording the number of lobbyists continues to be optional.** Nearly 65 percent of trade associations representing the pharmaceutical industry failed to record the number of lobbyists they employ.
- **Legislative proposals and debates lobbied on are not disclosed.** While registrants are invited to list their lobby activities in the register, it is not possible to know which pieces of legislation lobbyists are working on unless it is voluntarily disclosed. More precise information, such as which meetings were held with which EU officials and for which clients in the pharmaceutical industry, is virtually impossible to determine from the lobby register.

The pharmaceutical industry lobby has been linked to the EU's move to enhance data protection which is resulting in delays to marketing cheaper generic medicines. The industry lobby has also been implicated in EU member states' response to the so-called H1N1 Influenza, specifically through alleged mass-spending on insufficiently tested vaccines, posing unknown safety risks to those vaccinated.

The need to re-centre EU decision making around broader societal interests is at the heart of the move for greater lobby transparency. Citizens should have the right and the opportunity to participate in decisions that will affect their health and well-being. Without a clear view of the lobby resources and manpower wielded in Brussels, it is impossible to understand the powers at play behind these and other EU decisions.

³ As reported by EFPIA for the year 2010 in the EU Transparency Register, accessed by report authors on 29 January 2012. URL: <http://haieurope.org/wp-content/uploads/2012/03/TR-2010-EFPIA.pdf>

Introduction

The pharmaceutical sector is a top choice for any investor seeking a generous return on investment. Why? Many medicines are both lifesaving and lucrative. As inventions that prevent or treat disease, pharmaceuticals are an essential part of the healthcare system and not just another consumer product.

Medicines sales in Europe represent nearly a quarter of sales globally.⁴ According to The Financial Times, Pfizer's Lipitor, a medicine to treat high cholesterol, is expected to earn the company 3.3 million euros each day that it remains on patent in the European Union (EU) (Jack, 2011)⁵. With sizable profits at stake, the pharmaceutical industry has a vested interest in influencing any policy or decision-making process in the EU that can affect its products, its business and ultimately its shareholders.

The EU pharmaceutical industry lobby has been linked to the move to strengthen data protection, which consequently delays the marketing of generic medicines and keeps certain medicine prices high in Europe (Adamini, Maarse, Versluis, and Light, 2009). In a more recent example, Dr. Wolfgang Wodarg, who delivered an expert testimony concerning the so-called H1N1 pandemic to the Parliamentary Assembly of the Council of Europe, asserts that pharmaceutical industry influence could have deeper repercussions. According to his website, Dr. Wodarg links drug company influence to wasted public health resources and to safety risks that "needlessly expose[d] millions of healthy people to the risk of an unknown amount of side-effects of insufficiently tested vaccines" (Wodarg, 2009). Unchecked pharmaceutical industry influence on decision makers could not only impact the public and private purse, but it could also have disastrous effects on our health. Understanding the powers at play and having a reliable record of how affluent those interests are is a first step towards striking a balanced representation of stakeholders and reinforcing democracy in EU decision-making.

This report aims to expose the size and the approaches of the pharmaceutical sector to lobbying in the EU. This collection of examples of lobbying strategies takes a look behind the figures to show how the industry is putting its resources to work. Although the examples here are neither exhaustive nor representative of the whole sector, they do give insight into the

⁴ "According to data from IMA Health, 61% of sales of new medicines launched during the period 2005-2009 were on the US market, compared with 22% of the European market." (EFPIA, 2012).

⁵ This is calculated based on figures reported in the Financial Times concerning expected sales in the EU within a six month period as a result of Pfizer securing an SPC for Lipitor.

pharmaceutical industry's resources and *modus operandi*. The details of the survey design can be found in the Annex.

Why reveal lobbying in the EU?

The EU, Brussels and Strasbourg in particular, is the heart of decisions that will affect medicines in 27 EU countries and many nations beyond Europe. The EU has the power to legislate on intellectual property (IP) policies and competition laws that can affect cheaper generic medicines, as well as the approval of medicines for sale in Europe that are safe, effective and of high quality.

While EU policy has a tremendous effect on national legislation in Europe, some decisions about medicines are still made only at the national level. For example, only national policy makers decide which medicines will be reimbursed by the country's healthcare system. Pharmaceutical companies likely diffuse some of their lobbying resources among European countries. However, the EU wields a concentration of power not found at the national level. For example, the EU can expand companies' market access to countries outside the EU through trade agreements, resulting in generous global profits for drug makers. It is reasonable to expect companies to allocate the largest budget to lobby the EU government.

Why compare to the United States?

The pharmaceutical lobby is a wealthy player in US politics. At the height of the United States' healthcare debate in 2009, The Guardian newspaper reported that the pharmaceutical industry and interest groups spent 258 million euros (\$380m)⁶ in the course of several months to influence healthcare legislation through lobbying, advertising and in direct political contributions to members of Congress (McGreal, 2009). This information is available thanks to mandatory lobby disclosure rules and databases, such as OpenSecrets.org⁷, which harvest and crunch that data into easy-to-understand figures.

Europe's medicines sales rank second only to those in the United States.⁸ So, how does the EU's pharmaceutical industry lobby size up to that of its American counterpart? This report will

⁶ Exchange rate calculated using www.oanda.org on 7 October 2009, 1 USD = 0.67981 Eur

⁷ OpenSecrets.org was established by the Center for Responsive Politics in the United States.

⁸ "According to data from IMA Health, 61% of sales of new medicines launched during the period 2005-2009 were on the US market, compared with 22% of the European market." (EFPIA 2012)

compare what is known about the US Pharma lobby with new revelations on the EU's own medicines industry lobby.

Divide & Conquer

The pharmaceutical industry's lobby resources are diffused across three main lobby groups: in-house lobbyists employed within pharmaceutical companies, employees of trade associations which represent their members who are usually pharmaceutical companies or other trade associations, and third-party lobbyists-for-hire engaged by either companies or trade associations. This strategy could serve to dilute the perception of how much money is spent influencing the EU and how active the industry lobby is as a whole.

All active lobbyists are expected to voluntarily enter into the EU Transparency Register and disclose whose interests they are representing and what financing is behind those interests. The Transparency Register was set up and is operated by the European Parliament and the European Commission. It aims to offer "direct and single access to information about who is engaged in activities aiming at influencing the EU decision making process, which interests are being pursued and what level of resources are invested in these activities" (Transparency Register, 2012). The Register's shortcomings have been documented by the Alliance for Lobbying Transparency and Ethics Regulation (ALTER-EU)⁹. As this is the most transparent information available about lobby power in the EU, this report is based on declarations in the Transparency Register.

⁹ See ALTER-EU analysis "The missing millions: how the new lobby register needs to tackle the 'under-reporting' by industry lobby groups." Available at: <http://www.alter-eu.org/documents/2011/06/22/the-missing-millions-of-the-lobby-register>

Pharmaceutical companies

Number: Twenty-three companies were registered in the EU Transparency Register. These companies represent just one quarter of the total 72 member companies of trade associations European Federation of Pharmaceutical Industries and Associations (EFPIA)¹⁰. Their membership of EFPIA suggests that all 72 member companies have an interest in influencing the EU's economic, regulatory and political environment where their products are sold and used.¹¹

In the United States, the Open Secrets database houses records of lobbying spending of 92 pharmaceutical companies.¹² This disparity could, in part, be attributed to the fact that entering the EU register is voluntary for lobbyists, while lobby disclosure is mandatory in the United States (U.S. House of Representatives, 2012).¹³

Value: According to the EU Transparency Register, 23 pharmaceutical companies spend a combined total of 18.9 million euros on in-house interest representation annually.¹⁴ Based on these claims, each company invests on average 820,000 euros to influence EU policy formation and decision making, although this could be a drastic underestimation of the true value.¹⁵

The top 10 company spenders in Europe are listed below (see Figure 1). According to OpenSecrets.org, the lobby spending of these companies in the United States is more than twice their reported financing in Europe, even though no US lobby data exists for two of those companies.

¹⁰ Based on information retrieved from the EU Transparency Register between 15-30 January 2012

¹¹ "EFPIA's mission is to promote pharmaceutical research and development in Europe as well as creating a favourable economic, regulatory and political environment, enabling the research-based pharmaceutical industry to meet the growing healthcare needs and expectations of patients." (EFPIA, 2012b)

¹² Based on information retrieved from Center for Responsible Politics on 15 January 2012. Includes 108 entries of which 10 entries belong to a related industry association or council (not to a company).

¹³ According to the US Lobbying Disclosure Act of 1995 "No later than 45 days after a lobbyist first makes a lobbying contact or is employed or retained to make a lobbying contact, whichever is earlier, such lobbyist (or, as provided under paragraph (2), the organization employing such lobbyist), shall register with the Secretary of the Senate and the Clerk of the House of Representatives"

¹⁴ This figure was calculated based on information that was valid on 31 January 2012. It does not reflect subsequent changes as the EU Transparency Register can fluctuate daily. In most cases, companies specified that this excludes payments to membership associations and to third party representatives.

¹⁵ This figure was calculated based on information that was valid on 31 January 2012. It does not reflect subsequent changes as the EU Transparency Register can fluctuate daily.

Figure 1. Top 10 Company Spenders

Pharmaceutical company	Amount reported in the EU Transparency Register ¹⁶	Amount reported on OpenSecrets.org (USA) ¹⁷ for 2011
Bayer AG	€ 2,525,000	€ 3,322,880 (5.7m USD)
Merck Sharp & Dohme	€ 900,000	€6,170,530 (8.2m USD) ¹⁸
GlaxoSmithKline	€ 825,000 ¹⁹	€ 3,304,170 (5.4m USD)
Pfizer Inc.	€ 700,000	€ 8,007,840 (12.4m USD)
Novartis International AG	€ 700,000	€ 3,936,530 (5.8m USD) ²⁰
Genzyme Corporation	€ 600,000	- ²¹
SANOFI	€ 600,000	€ 3,283,960 (5.2m USD) ²²
Amgen Inc	€ 550,000	€ 5,470,780 (10m USD)
AstraZeneca	€ 500,000	€ 3,397,720 (4.5m USD) ²³
Baxter Healthcare SA	€ 500,000	- ²⁴
TOTAL	€ 8,400,000	€ 36,894,410

Highest figures reportedly spent in a 12-month period on interest representation by pharmaceutical company in the EU Transparency Register compared to data reported on OpenSecrets.org. Based on

¹⁶ Figures from 2011: Amgen Inc, GalaxoSmithKline, Novartis, Bayer; Figures from 2010-2011: Genzyme Corporation, SANOFI; Figures from 2010: AstraZeneca, Baxter Healthcare, Pfizer, MSD

¹⁷ Amounts companies spent on lobbying and political contributions in the USA in 2011, as reported on OpenSecrets.org in USD. Currency conversion calculated using the exchange rate on 1 Dec 2011 of 0.74840 EURO = 1 USD (www.oanda.org)

¹⁸ Amount reported on OpenSecrets.org for Merck Co. in 2011.

¹⁹ GSK reported spending €8,000,000 on interest representation in 2011 (URL: <http://haieurope.org/wp-content/uploads/2012/03/TR-2011-GSK.pdf> retrieved on 18 January 2012). That entry in the EU Transparency Register has subsequently been updated to report €825,000 (URL: http://haieurope.org/wp-content/uploads/2012/03/TR-2011-GSK_february.pdf updated 13 February 2012, retrieved 28 March 2012). Figure 1 has been amended to reflect this change.

²⁰ Sum of amount reported on OpenSecrets.org for Novartis Corp & Novartis Pharmaceuticals in 2011

²¹ No entry for Genzyme on OpenSecrets.org in 2011

²² Sum of amount reported on OpenSecrets.org for Sanofi Aventis & Sanofi-Pasteur in 2011

²³ Sum of amount reported by AstraZeneca Pharmaceuticals & MedImmune in 2011 on OpenSecrets.org

²⁴ No entry for Genzyme on OpenSecrets.org in 2011

information retrieved from the EU Transparency Register between 15-31 January 2012 unless otherwise indicated.

Europe's pharma giants would be expected to invest more in lobbying European governments on their home turf than foreign governments abroad. However, Danish drug giant Novo Nordisk reported spending over four times more to lobby the American government than to lobby the EU in 2011.²⁵ This sizable difference could be a sign of underreporting in the EU Transparency Register, stemming from the rigour of the reporting rules.

In an earlier version of this report, it was documented that British pharma heavyweight GlaxoSmithKline (GSK) reported an investment of 8 million euros in interest representation in 2011.²⁶ The figure for GSK's lobby expenditure in the EU Transparency Register was changed on 13 February 2012 to report a maximum of 825,000 euros, possibly to correct an entry error.²⁷ This highlights a very problematic aspect of the Transparency Register: registrants can change their data at any time and as there is insufficient oversight of these fluctuating figures, this means that the Transparency Register cannot be effectively used to gather general information on EU lobbying. Visitors of the register cannot be expected to verify each entry in the register with its author. The Alliance for Lobbying Transparency and Ethics Regulation in the EU (ALTER-EU) has been calling for the Commission and the Parliament to ensure that there is a robust monitoring system in place to verify lobby declarations.²⁸ There is also a need for clear guidance on disclosure requirements, including lobbying expenditure.

The United States has enforced mandatory registration of lobbyists and obligatory disclosure of their clients, other financial sources and lobbying expenditure.²⁹ Lobbyists and their clients must provide a good-faith estimate of their expenses rounded to the nearest 20,000 USD (OpenSecret.org, 2012). However, in the EU not all interest representatives appear in the EU Transparency Register because it is still voluntary. Moreover, information in the EU lobby

²⁵ As reported by NovoNordisk for the year 2011 in the EU Transparency Register, accessed on 30 January 2012; As reported on <http://www.opensecrets.org/lobby/induscode.php?id=H4300&year=2011> Accessed on 14 Jan 2012. Currency conversion calculated using the exchange rate on 1 Dec 2011 of 0.74840 EURO = 1 USD (www.oanda.org)

²⁶ As reported by GSK for the year 2011 in the EU Transparency Register, accessed by report authors on 18 January 2012. URL: <http://haieurope.org/wp-content/uploads/2012/03/TR-2011-GSK.pdf>

²⁷ As reported by GSK for the year 2011 in the EU Transparency Register, updated on 13 February 2012, accessed by report authors on 28 March 2012. URL: http://haieurope.org/wp-content/uploads/2012/03/TR-2011-GSK_february.pdf

²⁸ For more information, see ALTER-EU report "The missing millions – how the new lobby register needs to tackle the 'under-reporting' by industry lobby groups" June 2011, URL: <http://www.alter-eu.org/documents/2011/06/22/the-missing-millions-of-the-lobby-register>

²⁹ For more information, see speech by Siim Kallas, Vice-President of the European Commission responsible for Administrative Affairs, Audit and Anti-Fraud: "Lobbying: What the EU can learn from the US" (September 2007)

register must be updated at minimum once a year and failure to do so will result in temporary suspension from the Transparency Register and possibly restrict lobbyists' access to the European Parliament (Transparency Register, 2011). Registrations in the EU register are therefore less reliable than those in the American register, which must be updated more frequently with more precise information and which have strict sanctions for failing to abide by these rules (U.S. House of Representatives, 2011).³⁰ If reports from the EU Transparency Register are extrapolated to all 72 member companies of EFPIA alone, then the amount spent on lobbying in the EU could be closer to 59 million euros per year.³¹

Manpower: Fifteen companies in the EU Transparency Register each reported employing between one to 26 in-house lobbyists annually, with an average of six people per company. The EU Transparency Register reveals that there are at least 95 people employed by these companies to represent their interests in EU affairs, but the actual figure could be closer to 154 or more in-house lobbyists.³²

³⁰ The Frequently Asked Questions in the EU Transparency Register state that the Register secretariat does not check and validate entries upon registration. The minimum requirement is to update the information once a year. In contrast, the Guidance document for the US Lobbying Transparency Act states that each registrant must file a quarterly report on Form LD-2 no later than 20 days after the end of the quarterly period beginning on the first day of January, April, July and October of each year in which a registrant is registered. Sanctions for failing to do so within 60 days after notice include a civil fine up to \$200,000, among other penalties.

³¹ See calculation details in Annex C

³² See calculation details in Annex C.

Pharmaceutical industry trade associations

Pharmaceutical industry associations and related trade associations have been described as “richly funded and with skilled authorities on a topic, with ample time to help out in drafting legislation or the specifics of a regulation” (Adamini, Maarse, Versluis, and Light, 2009). These associations represent the interests of their members, who range from pharmaceutical companies to other industry associations.

Number: Twenty-two pharmaceutical trade associations have entries in the EU Transparency Register. The eight European associations reported to spend the most in the lobby register are reported in the figure below (see Figure 2).

The United States’ largest industry body, Pharmaceutical Research and Manufacturers of America (PhRMA), was absent from the EU lobby database despite representing several companies involved in EU affairs. Records from Wikileaks (2009, 2010) reveal that PhRMA also acts as an informant to the US government, monitoring EU governments’ protection of intellectual property rights (IPRs) and reporting on how European policies affect the interests of US pharmaceutical firms.

Value: The 22 pharmaceutical trade associations claim to spend a total of 2.3 million euros on representing their members, who range from pharmaceutical companies to other pharmaceutical industry associations.

EFPIA, Europe’s main pharmaceutical industry association, reported an investment of less than 50,000 euros for interest representation in 2010.³³ For activities in 2011, that figure jumps to 571,900 euros.³⁴ Considering that EFPIA consistently reports employing 10 staff members whose work falls under the scope of the Transparency Register, their 2010 claim could be a sign of underreporting. EFPIA’s reported spending pales in comparison to its US counterpart, PhRMA, which spent over 18 times more – 10.5 million euros - to influence the US government in 2011.³⁵

³³ As reported by EFPIA for the year 2010 in the EU Transparency Register, accessed by report authors on 29 January 2012. URL: <http://haieurope.org/wp-content/uploads/2012/03/TR-2010-EFPIA.pdf>

³⁴ As reported by EFPIA for the year 2011 in the EU Transparency Register, updated by EFPIA on 4 March 2012, accessed by report authors on 27 March 2012. URL: <http://haieurope.org/wp-content/uploads/2012/03/TR-2011-EFPIA.pdf>

³⁵ Calculated from the lobbying expenditure attributed to PhRMA in 2011 on <http://www.opensecrets.org/lobby/clientsum.php?id=D000000504&year=2011> Accessed on 15 Jan 2012. Currency conversion calculated using the exchange rate on 1 Dec 2011 of 0.74840 EURO = 1 USD (www.oanda.org).

Figure 2. Top European Trade Association Spenders

Company Name	Amount reported in the EU Transparency Register³⁶
European Federation of Pharmaceutical Industries and Associations	€ 571,900
Association of the European Self-Medication Industry	€ 150,000
European Vaccine Manufacturers	€ 150,000
European Biopharmaceutical Enterprises	€ 150,000
European Generic Medicines Association	€ 100,000
European Alliance for Cost Efficiency in Healthcare	€ 100,000
European Confederation of Pharmaceutical Entrepreneurs	€ 100,000
Plasma Protein Therapeutics Association	€ 50,000
TOTAL	€ 921,900

Figures reportedly spent by European trade associations in a 12-month period on representing the pharmaceutical industry, according to the Transparency Register. Based on information retrieved from the EU Transparency Register between 15-31 January 2012.³⁷

Manpower: Eight associations in the EU Transparency Register each reported employing between one to 25 lobbyists, with an average of six EU affairs representatives per association. Fourteen associations did not indicate how many lobbyists they employ.³⁸

Assuming that the other 14 associations employ at least one person to represent their interests to the EU, European trade associations are estimated to employ a total of 62 or more pharmaceutical lobbyists.³⁹

³⁶ Figures from 2011: European Confederation of Pharmaceutical Entrepreneurs, European Federation of Pharmaceutical Industries and Associations, Plasma Protein Therapeutics

Figures from 2010: Association of the European Self-Medication Industry, European Vaccine Manufacturers, European Biopharmaceutical Enterprises, European Alliance for Cost Efficiency in Healthcare

Figures from 2009: European Generic Medicines Association

³⁷ Figure for EFPIA is updated to reflect their declared spending in 2011, accessed by report authors on 27 March 2012. URL: <http://haieurope.org/wp-content/uploads/2012/03/TR-2011-EFPIA.pdf>

³⁸ Based on information retrieved from the EU Transparency Register between 15-31 January 2012.

National trade associations

National trade associations have a vested interest in influencing EU law, yet national trade groups representing research-based pharmaceutical companies were nearly entirely absent from the EU register. Six associations from Germany, Belgium, Ireland and France submitted written responses to the EU's public consultation on a review of the Clinical Trials Directive in 2011, yet only three of those associations could be traced in the EU Transparency Register (European Commission, 2012).

Association of British Pharmaceutical Industries (ABPI)

The ABPI was also curiously absent from the EU lobby register despite having a lobby footprint in Brussels dating back to 2000 (Corporate Watch, 2003). With member companies who supply 90 % of all medicines used by the National Health System (NHS) in the United Kingdom, ABPI has a keen interest in influencing policies in Brussels that could affect that market. ABPI has been a long-time player working to loosen the EU's ban on medicines advertising. Studies tell us that increased medicines promotion is usually associated with increased sales (WHO, 2004). In 2000, ABPI outlined its "battle plan" to introduce direct-to-consumer-advertising in a briefing to the Pharmaceuticals Marketing Society:

"to deploy ground troops in the form of patient support groups, sympathetic medical opinion and healthcare professionals [...]. 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 [...]." (Corporate watch, 2003)

ABPI does not maintain an entry in the EU Transparency Register despite its recent submission to the European Commission's public consultation on the Clinical Trials Directive in 2011. Participating in Commission consultations is not dependent on being entered in the EU Transparency Register.

³⁹ See calculation details in Annex C.

American business associations in Europe

Given the sheer size of the US pharmaceutical industry, it is no surprise that companies also engage American business associations, such as the American Chamber of Commerce to the European Union, the Trans-Atlantic Business Dialogue, and the European-American Business Council (EABC), to vie for their interests in the EU.

According to EABC, it hosts multiple members-only roundtable discussions with senior US & EU officials each year (EABC, 2008). In 2010, the EABC boasted two private events involving member pharmaceutical companies: the Life Sciences Dinner with selected Members of the European Parliament (MEPs), European Parliament Staff, Commission Officials and Bayer; and the TEC & Trans-Atlantic Innovation Dialogue, with member company Lilly (EABC, 2008a). By comparison, public interest organisations can face difficulty reaching EU officials. At the annual Brussels meeting of the Trans-Atlantic Consumer Dialogue (TACD) in June 2011, the European Commission did not send an official to join the access to medicines discussion with consumer organisations from across the EU and US, despite repeated invitations.

Consultancies hired by the pharmaceutical industry

Number: The EU Transparency Register revealed that at least 24 consultancies provide lobby services to the pharmaceutical industry.⁴⁰ Several consultancies may be employed by the same company, as is the case of Johnson & Johnson which employed at least five different consultancies in the same year to represent its interests (see Figure 3).⁴¹

Value: Consultancies spent an estimated total of 19.2 million euros representing clients in the pharmaceutical industry, according to reports in the EU Transparency Register. Figure 3 shows the top 10 lobby consultancies that reported spending the most money for their drug industry clients.

The entries in the lobby register, however, are far from precise, as consultancies need only report income from each client in ranges of €50,000, € 100,000 or €250,000 wide, depending on the size of the contracts. The above estimate is based on the average amounts declared. If we consider the maximum spending declared, consultancies could have spent as much as 30.1 million Euros in total representing pharmaceutical industry clients.⁴²

Figure 3. Top 10 highest lobby consultancy spending for pharmaceutical industry clients

Company Name	Ratio of pharmaceutical industry clients to all clients	Estimated total amount spent on representing pharmaceutical industry clients ⁴³	Pharmaceutical industry client list reported on EU Transparency Register
Burson-Marsteller	7:44	€ 1,675,000	Bayer Schering Pharma Pfizer Johnson & Johnson Novartis

⁴⁰ Sum of consultancies representing pharmaceutical industry clients in 2009, 2010 or 2011

⁴¹ Based on information retrieved from the EU Transparency Register on 15 January 2012.

⁴² See calculation details in Annex C. Calculations were made using data retrieved between 15-31 January 2012.

⁴³ Figures from 2011 entries: Hill & Knowlton International Belgium, Cabinet DN Consulting

Figures from 06/2010 – 06/2011: Edelman Public Relations Worldwide

Figures from 2010 entries: Burson-Marsteller, Fleishman-Hillard, Rohde Public Policy, FIPRA International Ltd., APCO Worldwide, Weber Shandwick, G Plus Ltd.

			Eli Lilly Celgene NovoNordisk AstraZeneca Amgen LeoPharma Bristol-Myers Squibb European Vaccine Manufacturers Genzyme
Hill & Knowlton International Belgium	6:23	€ 1,365,000	Johnson & Johnson Novartis AstraZeneca Bristol-Myers Squibb Amgen Lundbeck
Fleishman-Hillard	3:65	€ 1,068,173	Johnson & Johnson Merck Serono Pfizer
Rohde Public Policy	6:11	€ 900,000	Abbott Baxter Boehringer Ingelheim Essex Gilead Merck Serono Merck Sharp & Dohme ViiV Healthcare European Biopharmaceutical Enterprises Bristol-Myers Squibb Protein Plasma Therapeutics Association Alexion Pharma
FIPRA	3:22	€ 700,000	GSK

International Limited			Lilly Europe Novartis Pfizer AMD Gilead
Edelman Public Relations Worldwide⁴⁴	7:54	€ 525,000	AstraZeneca Baxter GSK Pfizer Johnson & Johnson Novartis Roche
APCO Worldwide	5:41	€ 325,000	Shire Johnson & Johnson EFPIA Novartis Hoffmann-LaRoche
Cabinet DN Consulting	1:21	€ 300,000	Amgen LFB (Biotechnologies)
Weber Shandwick	3:37	€ 275,000	Merck Serono Celgene Abbott Laboratories
G Plus Ltd.	1:12	€ 175,000	Baxter GSK Boehringer Ingelheim
Total		€ 7,308,173	

Estimated average reportedly spent in a 12-month period by consultancies representing pharmaceutical industry clients, according to the EU Transparency Register. Based on information retrieved from the EU Transparency Register on 15 January 2012 unless otherwise indicated.

Curiously, nine pharmaceutical companies hired consultancies while the drug companies themselves do not have an entry in the lobby register. Boehringer Ingelheim is the most striking

⁴⁴ Based on data retrieved from the EU Transparency Register on 30 January 2012.

example of a company as it remains undocumented in the EU Transparency Register despite engaging five consulting firms over the period of two years, suggesting that the company has an interest in influencing these policy debates.⁴⁵

Manpower: Based on the number of staff members and clients declared in the EU Transparency Register, consultancies are estimated to employ at least 66 lobbyists to represent pharma industry clients exclusively.⁴⁶ This figure could be higher depending on the distribution of working hours between staff members and taking into account that some client accounts are bigger than others. This estimate does not include short-term agreements with outside consultants who are not reported in the EU Transparency Register.

⁴⁵ This information was retrieved on 15 January 2012.

⁴⁶ See calculation details in Annex C.

Persistent flaws in the EU Transparency Register

Organisations engaged in lobbying fail to sign-up to the register: At least six pharmaceutical companies engaged with the Directorate General for Health and Consumer Affairs (DG SANCO) in 2011 but do not maintain an entry in the Transparency Register. Neither do an additional six companies who hired various lobby firms to represent their interests to the EU.⁴⁷ These 12 companies represent half of those companies who have entries in the lobby register.

Underreporting still plagues entries in the register: EFPIA reported an investment of 50,000 euros in EU interest representation in 2010, despite claiming to employ 10 staff members whose work falls under the scope of the Transparency Register.⁴⁸ Declared lobby spending that is insufficient to support the reported number of staff could be a sign of underreporting.

The financial information in the lobby register is far from precise: Consultancies, companies and trade or professional associations can choose to report their lobby spending in ranges of €50,000, € 100,000 or €250,000 wide, depending on their total lobbying turnover. Moreover, consultancies need only report income from each client in similar ranges of different size depending on the size of the contract.

Recording the number of lobbyists continues to be optional. Nearly 65% of trade associations representing the pharmaceutical industry failed to record the number of lobbyists they employ.

Legislative proposals and debates lobbied on are not disclosed. While registrants are invited to list their lobby activities in the register, it is not possible to know which pieces of legislation lobbyists are working on unless it is voluntarily disclosed. More precise information, such as which meetings were held with which EU officials and for which clients in the pharmaceutical industry, is virtually impossible to determine from the lobby register.

⁴⁷ Based on information retrieved from the EU Transparency Register between 15-31 January 2012.

⁴⁸ Based on information retrieved from the EU Transparency Register on 29 January 2012.

Influence strategies: Behind the price tag

The pharmaceutical industry follows a lobby pattern. Lobbyists first make contact with politicians on general health matters or “soft” issues. Perhaps it is an invitation to ad hoc breakfast briefings at the EFPIA offices in Brussels. Or perhaps it is one of the many industry-sponsored events in the European Parliament that facilitate that initial communication between politician and lobbyist. Then, as specific legislative opportunities arise, lobbyists make use of their established network to diffuse their messages to targeted politicians on “hard” issues.⁵⁰

Pharma lobbyists do not have to do much traditional pavement-pounding nor do they need to go door-to-door, canvassing politicians like traveling salespeople. The pharmaceutical industry has good contacts with key people in populous political groups. The job of the industry lobbyist is to maintain these relationships.⁵¹

The cases below are examples of these strategies in action.

⁵⁰ This information was reported in anonymous interviews.

⁵¹ This information was reported in anonymous interviews

Thank you for smoking

Figure 5. Pfizer publication from Portugal



Pfizer publication from Portugal (2007) reads “More than 6 weeks without smoking and no arguments yet. Stop smoking without dramas. Visit your doctor.”

According to the EU Transparency Register, Pfizer hired corporate consultancy Edelman The Center to represent its interests between 2010-2011.⁵² Edelman has employed Nick Fahy, former Head of Unit for Health Information in DG SANCO, who describes his work at Edelman as “explaining how the EU works to pharmaceutical companies” (DG SANCO, 2011). This revolving door case sees a seasoned EU official with over 10 years of experience in DG SANCO⁵³ move to provide services for the pharmaceutical industry within months of leaving his public post. Revolving doors carry the risk that personal contacts and inside knowledge acquired while in the public service could be used to benefit private companies. In e-mail correspondence with his former boss, Fahy notes that he is conscious of avoiding conflicts of interest by not using information that is only available within the European Commission (DG SANCO, 2011).

⁵² Based on a report from Edelman Public Relations Worldwide in the EU Transparency Register for 7/2010 – 6/2011, retrieved on 30 January 2012.

⁵³ Nick Fahy CV. Available at: http://www.nickfahyconsulting.eu/Nick_Fahy_CV.pdf [Accessed 31 January 2012]

Staff from Edelman The Center contacted DG SANCO in 2010 concerning a forthcoming tender for the “organisation of a communication campaign aimed at encouraging smoking cessation” (Edelman, 2010). Although smoking may seem unrelated to medicines, Edelman’s client, Pfizer, has an interest in people “kicking the habit”. Why? Pfizer sells a product to help people quit smoking.

Pfizer ran a campaign in Portugal announcing “Stop smoking without dramas”. This 2007 publication flirts with the edges of the EU-wide ban on medicines advertising because Pfizer, whose logo is visible in the full-page publication, also sells a smoking cessation product available on prescription only (see Figure 5).

Pfizer has since joined forces with GSK, Boehringer Ingelheim and the European Respiratory Society to found the European COPD Coalition (ECC). Chronic obstructive pulmonary disease (COPD) is a condition caused by two co-existing lung diseases, bronchitis and emphysema, that cause a narrowing of the airways. ECC describes itself as an alliance of stakeholders involved in preventing and treating COPD, and caring for COPD patients (ECC, 2012). The Coalition is reaching out to Parliamentarians and MEP Glenis Willmott is on board, reporting on her website, “I have been getting involved with the newly formed European COPD Coalition as we look towards revising the Tobacco Products Directive next year” (Willmott, 2011). Stricter legislation on tobacco products is a reasonable objective, yet it would be more transparent for Ms. Willmott to make it publicly clear that she is consulting with an organisation representing several pharmaceutical companies, including Pfizer which produces a medicine to aid smoking cessation.

Debate with the Dinosaurs

Novartis opted for a novel destination for its EU policy discussion on antibiotic innovation: Museum des Sciences Naturelles, commonly known as the ‘Dinosaur Museum’ in Brussels. Invitations were reportedly sent to a host of EU institutions that yielded a mix of Council and Commission officials, staff from the European Parliament and Permanent Representations as well as NGOs for a lunch seminar. Networking at this event was sure to be memorable, taking place in the Whales Room among “a truly huge group of sea mammals: dolphins, bottlenose dolphins, sperm whales, baleen whales, walruses, manatees” (Museum, 2012).

Several institutions are needed to adopt new legislation, from the European Commission which drafts proposals, to staff from the Permanent Representations who negotiate on behalf of their

governments, to MEPs and their teams. Pharmaceutical industry lobbyists need to target both member states in the Council, as well as members of the European Parliament, as both institutions decide on legislation.

EFPIA's privileged access to EU trade officials & access to medicines in developing countries

EFPIA stays in close contact with trade officials at the European Commission on IP issues that could affect profits from medicines. In September 2009, Europe's pharmaceutical companies had just cause to be concerned: the EU had dropped their demand for an extended data exclusivity period towards the end of week-long trade negotiations with Peru and Colombia (HAI Europe, 2011).

Data exclusivity is a form of data protection that prevents competitors from launching their cheaper generic medicines on the market. In a global comparison, Peru is among the countries with low medicine prices and those that spend the least on pharmaceuticals per person⁵⁴. A trade agreement that limits the competition of medicines could drive prices in Peru up, securing greater profits for drug companies at the expense of widespread access.

A few weeks later, EFPIA sounded the alarm following media reports that the European Commission could be willing to make more concessions on IPRs in its negotiations with the Community of Andean Nations (Bruce, 2009). According to e-mail correspondence, EFPIA contacted DG Enterprise to drum up extra support for their position within the European Commission, possibly seeking to exert pressure on DG Trade from within (DG Enterprise, 2009).

DG Enterprise officials were less receptive to the concerns of civil society. While they did host stakeholder consultations and accept invitations to panel discussions, DG Enterprise "mostly dismissed our concerns for health and development, arguing for the competitive edge of European business and the need for jobs in Europe. Officials denied the impact that these trade deals could have on access to medicines in Peru and Colombia in spite of evidence from impact studies," explains Sophie Bloemen, trade campaigner at Health Action International (HAI) Europe. In the end, Peru and Colombia did sign the free trade agreement with the EU, although the most harmful provisions were scaled back in the final text.

⁵⁴ based on their per capita income

Allegations of “powerful” industry influence over EU decision makers linked to decisions that threaten the affordability of medicines in Europe

Before the “Big Bang” accession of mainly central and eastern European countries to the EU in 2004, Europe witnessed the hasty revision of legislation on data exclusivity that postponed generic medicines competition in the EU. Such a move threatened medicines affordability in Europe, particularly for the accession countries in Central and Eastern Europe where national laws provided for shorter periods of data protection or none at all. Europe’s pharmaceutical industry had an interest in securing monopolies for its products in these unprotected markets.

The political powers at play have been studied by researchers from Maastricht University and Duke University who interviewed civil servants, lobbyists and public health advocates to understand how industry interests shaped this legislative review. The results, summarised below, can be accessed in the article “Policy Making on Data Exclusivity in the European Union: From Industrial Interests to Legal Realities” (Adamini, Maarse, Versluis and Light, 2009).

As the European Commission holds the power to propose legislation, a Danish civil servant reported that industry was “quite naturally [...] keen to aid and abet the Commission, hoping thereby to promote its own points of view” at the onset of the revision (Adamini et al., p 994). The Commission’s relationship with research-based pharmaceutical industry had already been labeled “clientilistic,” suggesting this EU institution has a service provider-client relationship with the private pharmaceutical sector (Adamini et al., p 994). During the drafting process, it was reported that there was constant contact between DG Enterprise and EFPIA, although this was stated as completely normal: “Of course we [the Commission] have many direct contacts with the industry [...] they are supposed to produce the medicines. They know best in the end” (Adamini et al., p 995). The authors note that the proposal adopted by the Commission was in line with what EFPIA requested in its 1999 policy paper, despite alternatives proposed by the European Generic Medicines Association (Adamini et al., p 994).

Where were public interest advocates throughout this process? The European Public Health Alliance (EPHA) reportedly had 3.5 full time employees at the time to tackle “the entire public health agenda” - data exclusivity being a very small sub-set of the pharmaceuticals portfolio (Adamini et al., p 996). HAI remarked that it was “doing the best it can with painfully limited resources” (Adamini et al., p 995). A collective of consumer, patient and insurance organisations, the Medicines in Europe Forum (MiEF) entered the lobby arena in 2002, claiming that this review did not account for the public health perspective (Adamini et al., p 999). With the

European Commission's proposal already on the table, MiEF focused its efforts on the European Parliament, albeit without overwhelming success. Accounts from a Danish civil servant point out that, "the influence of the industry on various MEPs was to a large degree obvious from the language of many amendments" (Adamini et al., p 999).

In summary, a public health lobbyist interviewed by the study authors describes this legislative review as:

"The most appalling example of mis-governance, because the extension of data exclusivity was pushed through and the pharmaceutical review was fast-tracked before enlargement [the accession countries] were totally ignored. Frankly, the interests of the industry were largely based in countries like France, the United Kingdom, and Germany, prevailed over the wider solidarity issue or even the general health issues." (Adamini et al., p 1001)

Behind the patient group campaign calling for 'patents for life'

The Genetic Interest Group (GIG), representing patients with genetic diseases, had been profiled as long-time opponents of attempts in the EU to patent genes. Curiosity sparked in July 1997 when wheelchair-bound protesters organized by GIG's Director greeted MEPs arriving at the European Parliament to vote on the so-called Life Patent Directive, legislation that would patent genes, cells, plants, animals, human body parts and genetically modified or cloned human embryos – something GIG had previously opposed (Lobbywatch.org). Protesters called on MEPs to vote to pass the proposal into law. Pamphlets reportedly handed to MEPs asking "how it was that you had the opportunity to create significant progress in the search for cures, but you chose not to take that step?" have been labeled as nothing short of "emotional blackmail" (Lobbywatch.org). The lobbying is said to have been a decisive factor in the European Parliament's approval of the Directive, which MEPs had vetoed just two years earlier. The plot thickens as the Chair of GIG is reported to have issued a letter following the wheelchair stunt, restating that the group was against gene patents (Balanyá et al., 2000).⁵⁵

GIG's impressionable political agenda has been linked to its sponsorship⁵⁶ by pharmaceutical company SmithKline Beecham, which was said to be lobbying aggressively for the Patent Life

⁵⁵ This case is mentioned in a chapter in *Europe Inc.: Regional & Global Restructuring and the Rise of Corporate Power* Written by: Belén Balanyá, Ann Doherty, Olivier Hoedeman, Adam Ma'anit and Erik Wesselius. London: Pluto Press, January 2000.

⁵⁶ Sponsorship is reported to include receiving expenses and 'gifts in kind'

Directive. SmithKline Beecham's support for GIG was also reported to include the hiring of the lobby firm GPC Market Access, which later joined the Fleishman-Hillard consultancy family (Power Base, 2010).

For hire: Brussels-bubble print media

Figure 6. Cover of The Parliament Magazine summer 2009 supplement titled *Fake Medicines*, sponsored by American pharmaceutical giant Lilly.



The Parliament Magazine ran a supplement on Fake Medicines in summer 2009 amid the EU-wide debate about falsified medicines, considered to be medicines containing the wrong active ingredient or an active ingredient in the wrong quantity⁵⁷. Brussels-bubble print media like The Parliament Magazine is based on editorial and advertorial contributions from a variety of politicians and interest groups, offering lobbyists the opportunity to present their messages in a magazine that is reported to reach everyone from European Commission staff to high level policy makers (Wikipedia 2011). More importantly, the industry lobby can take advantage of the opportunity to show broad support through a variety of editorials written by different stakeholders.

Eli Lilly sponsored the supplement of The Parliament Magazine which focused on key issues in the falsified medicines debate. Although each editorial emphasizes different priorities in the

⁵⁷ For more information, see DG SANCO webpage on Falsified Medicines: http://ec.europa.eu/health/human-use/falsified_medicines/index_en.htm

counterfeits debate, Eli Lilly's spokesperson draws attention to stakeholders' unified concern to eliminate the threat of counterfeit drugs without divulging the company's specific position on the proposal nor the company's products that would be affected by future legislation. Collective, multi-stakeholder support corroborates Eli Lilly's political agenda to reduce threats to its top products that are targeted by counterfeiters: medicines to treat schizophrenia and bipolar disorder (Press Association, 2010), and erectile dysfunction (EurActiv, 2010).

Curiously, Eli Lilly's technical position paper on the European Commission's counterfeit medicines proposal remains inaccessible. The company requested that their submission to the Commission's public consultation on the Falsified Medicines Directive in 2008 remain confidential. Consequently, it is not published on DG SANCO's webpage together with the 125 other responses from European patient and consumer groups, individuals, healthcare professional groups, pharmaceutical companies and industry associations. This marked absence raises questions about the company's true views on the Falsified Medicines Directive and why they cannot be shared publicly alongside other stakeholders' submissions.

Clinical Trials

2011 was an active year in the run-up to a new proposal expected from the European Commission in 2012 to amend the Clinical Trials Directive. Sanofi-Aventis, a French drug company, sponsored a lunch debate in the Parliament in March 2011 (Groupe PPE, 2011). The company later hosted a field visit to its clinical research premises in France and arranged for a delegation of EU officials to gain a deeper understanding of issues affecting clinical trials. Later in the year, EuropaBio, the trade association for bio-industries, hosted a Parliamentary Workshop on the "Benefits of a simplified and coherent clinical trials framework in Europe" (Juvin, 2011). These events are opportunities to communicate key messages and to make crucial contacts before the European Commission's draft proposal is expected to reach the European Parliament and Council in 2012.

Just the tip of the iceberg?

Conservative estimates suggest that the entire pharmaceutical industry lobby is spending 40 million euros to influence EU affairs annually.⁵⁸ This report demonstrates that that figure could be as high as 91 million euros after considering the underreporting stemming from imprecise, nontransparent and even absent declarations in the EU Transparency Register.⁵⁹ Companies and industry associations have failed to join the voluntary register in spite of their documented efforts to influence EU medicines policy. This estimate is comparable to pharma's lobby footprint in the United States, where the pharmaceutical manufacturing sector has reportedly spent about 85,5 million euros (115,571,832 USD) in lobbying the American government in 2011 (Love, 2011).

About 220 lobbyists are estimated to be active in the EU on behalf of the pharmaceutical industry, based on the sum of the figures in this report. This number pales in comparison to the 1498 pharmaceutical industry lobbyists documented in the United States in 2011⁶⁰ (Center for Responsive Politics, 2011). Clear and enforced reporting rules in the United States yield a more accurate picture of pharma's lobby contingent in America as compared to the EU.

On the other hand, nine civil society groups active on EU medicines issues spent a meager 3.4 million euros per year on advocacy in EU affairs.⁶¹ The most affluent of these organisations tackle a range of issues, from the entire public health agenda in the case of the EPHA, to the diversity of consumer issues for the European Consumers' Organisation (BEUC) and Which?. The AGE Platform promotes the interests of senior citizens in the EU, addressing health and long term care alongside issues of gender equality, employment and tackling the digital divide. Even when considering the possibility of underreporting, civil society's resources do not hold a candle to the Pharma industry's lobbying affluence.

The need to re-centre EU decision-making around broader societal interests is at the heart of the move for greater lobby transparency. Citizens should have the right and the opportunity to participate in decisions that will affect their health and well-being. As described above, past

⁵⁸ This figure is valid on 31 January 2012. It does not reflect subsequent changes in the EU Transparency Register.

⁵⁹ This figure is valid on 31 January 2012. It does not reflect subsequent changes as the EU Transparency Register.

⁶⁰ This figure includes all interest representatives from the sector (i.e. in-house representatives, lobbyists for industry associations and lobbyists from law firms or PR firms hired by clients)

⁶¹ This is the sum of the maximum reported spending on interest representation activities in the EU Transparency Register for a 12-month period by nine civil society groups. See Annex B for inclusion criteria and Annex C for the calculation method.

examples have linked the industrial lobby to EU policy decisions that have a negative impact on access to affordable and safe medicines. Without a clear view of the lobby resources and manpower wielded in Brussels, it is impossible to understand the powers at play behind these and other EU decisions. In the words of Siim Kallas, former Commissioner for Administrative Affairs, Audit and Anti-Fraud: "Nobody would pay real money for lobby without expecting 'something' in return and that 'something' is influence!" (Kallas, 2007). It becomes even more difficult to level the policy playing field considering the immense disparity between the affluence of public interest groups and corporate lobbyists.

Annex A: Inclusion criteria for corporate lobbyists

The list of pharmaceutical industry lobbyists was developed by:

1. Identifying the representatives of the pharmaceutical industry lobby who responded to the public consultations hosted by the European Commission on the Information to Patients Directive (European Commission, 2008) and the Clinical Trials Directive (2010) (European Commission, 2012), including those respondents whose contributions were kept confidential. These respondents were included in the list of lobbyists.

In the case of the Clinical Trials Directive, included respondents were: pharmaceutical companies, trade associations representing the pharmaceutical industry, regulatory affairs consultancies. Excluded respondents were: individuals, universities, research institutes, insurance associations, patient organisations, healthcare professionals, medical societies, contract research organisations, statutory bodies, regulatory authorities, ethics commissions.⁶²

2. Retrieving the list of members of any European membership-based associations that responded to either of the above public consultations.

European membership-based associations included on the list of lobbyists were those with more than 50% of their members being from the pharmaceutical industry, namely: Association of International Pharmaceutical Research Group, Association of the European Self-Medication Industry, European Federation of Pharmaceutical Industries and Associations (EFPIA) including the European Biopharmaceutical Enterprises and the European Vaccine Manufacturers, European Generic Medicines Association, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), European Medicines Group, Plasma Protein Therapeutics Association (PPTA).⁶³ For this reason, associations such as EuropaBio and the Nanotechnology Industries Association were excluded.

3. Searching for the companies and associations identified above by name in the EU Transparency Register, using the function 'search by word or expression'. Identify any consulting firms that list the company or association as a client and add those firms to the list of lobbyists. Law firms were excluded from the list of lobbyists.

⁶² Although these organisations were not included in the list of lobbyists, some of these groups may be funded by the pharmaceutical industry.

⁶³ Including PPTA's global, European and North America members. Excluding source and affiliate members. <http://www.pptaglobal.org/member/default.aspx>

Annex B: Inclusion criteria for civil society advocates

Inclusion criteria:

- Organisation is independent of funding from the pharmaceutical industry
- Organisation maintains an entry in EU Transparency Register

The list of civil society organisations active on EU medicines issues was further refined to those:

- who responded to either of the public consultations on the clinical trials directive or to the information to patients directive, or
- whose entry in the EU Transparency Register was found by searching for the term 'pharmaceutical,' or
- who are members of the European Medicines Agency Patients and Consumers Working Party.

Annex C: Method used to calculate lobbying expenditure

All information from the EU Transparency Register was retrieved between 15-31 January 2012, unless otherwise indicated.

Pharmaceutical companies

Number: 133 companies were identified according to the inclusion criteria and included in the search of the EU Transparency Register, including member companies of European Federation of Pharmaceutical Industries and Associations, European Generic Medicines Association, European Confederation of Pharmaceutical Entrepreneurs, and European Medicines Group. Only the entries of 23 companies could be located on 30 January 2012.

Value: 18.9 million euros represents the sum of the maximum amounts spent on activities related to the EU Transparency Register reported by 23 companies.⁶⁴ According to this data retrieved and computed on 31 January 2012, the average investment per company is 820,000 euros in a 12-month period.⁶⁵

If a lobby investment of 820,000 euros were attributed to each of the 72 EFPIA member companies, then the amount spent by this group of companies on lobbying in the EU could be closer to 59 million euros per year.⁶⁶

Manpower: 15 companies reported employed a total of 95 people to work in EU affairs in the EU Transparency Register. Thirteen of those companies are members of EFPIA. The remaining 59 EFPIA member companies could have at least one employee working in EU affairs, yielding a total of 154 people employed as in-house representation.

Trade associations

Number: 90 trade associations were identified according to the inclusion criteria and included in the search of the EU Transparency Register. This number included the national association members of Association of the European Self-Medication Industry, EFPIA, European Generic Medicines Association, and European Confederation of Pharmaceutical Entrepreneurs. Only the

⁶⁴ This figure is valid on 31 January 2012. It does not reflect subsequent changes to the EU Transparency Register.

⁶⁵ This figure is valid on 31 January 2012. It does not reflect subsequent changes as the EU Transparency Register.

⁶⁶ This figure is calculated based on data valid on 31 January 2012. It does not reflect subsequent changes to the EU Transparency Register.

entries of 22 trade associations could be located in the register: eight European associations (see Figure 2) and 14 national associations active at the EU level.⁶⁷

Value: 2.3 million euros is the sum of the maximum amount reportedly spent on activities related to the EU Transparency Register by the 22 pharmaceutical trade associations in a 12 month period.⁶⁸

Manpower: Eight associations reported employing a total of 48 people to work in EU affairs.⁶⁹ The remaining 14 associations in the EU Transparency Register are estimated to employ at least one lobbyist, yielding a total of 62 people employed as lobbyists for trade associations.⁷⁰

Consultancies

Number: 24 consulting firms were identified in the search of the EU Transparency Register on 30 January 2012.

Value: Consulting firms indicated in the EU Transparency Register which clients generated turnover within a range of +/- 50,000 euros. Typical increments were: less than 50,000 euros; 50,000-100,000 euros; 100,000 – 150,000 euros, etc.

In few cases, firms indicated that clients generated a percentage of their turnover, rather than a range of +/- 50,000 euros. For the purposes of estimation, when the firm's turnover was not declared in the EU Transparency Register, it was assumed to be the maximum amount the consultancy declared spending on EU representation activities.

The estimated total value of representation by all consultancies in the EU Transparency Register is 19.2 million euros.⁷¹ To illustrate the calculation method, consider a consultancy serving:

- Three pharmaceutical companies reported to generate between 0 and 50,000 euros, and,
- One pharmaceutical company reported to generate between 50,000 euros and 100,000 euros.

⁶⁷ This figure is valid on 31 January 2012. It does not reflect subsequent changes to the EU Transparency Register.

⁶⁸ This figure was calculated based on data retrieved between 15-31 January 2012. The calculation was updated to include EFPIA's updated figures in the EU Transparency Register on 4 March 2012.

⁶⁹ This figure is valid on 31 January 2012. It does not reflect subsequent changes to the EU Transparency Register.

⁷⁰ This figure is valid on 31 January 2012. It does not reflect subsequent changes to the EU Transparency Register.

⁷¹ This figure is valid on 31 January 2012. It does not reflect subsequent changes to the EU Transparency Register.

The total value of the services provided by this consultancy to clients in the pharmaceutical industry was calculated to be:

$$[3 \text{ companies} \times 25,000 \text{ euros}] + [1 \text{ company} \times 75,000 \text{ euros}] = 150,000 \text{ euros turnover}$$

The turnover from pharmaceutical industry clients for each of the 24 consulting firms totals 19.2 million euros.

The estimated maximum value of the services provided by consulting firms to clients in the pharmaceutical industry is 30.1 million euros.⁷² To illustrate the calculation method, consider the above example of the consulting firm. The maximum value of the services it provided to the pharmaceutical industry is:

$$[3 \text{ companies} \times 49,000 \text{ euros}] + [1 \text{ company} \times 99,000 \text{ euros}] = 246,000 \text{ euros turnover}$$

The maximum turnover generated by pharmaceutical industry clients for each of the 24 consulting firms totals 30.1 million euros.⁷³

Manpower: The number of hired consultants working for pharmaceutical industry clients was estimated by first assuming that the staff reported by a consulting firm in EU Transparency Register work an equal number of hours for each client.

Then the number of staff per firm who are dedicated to representing pharmaceutical industry clients was calculated using this formula:

$$\frac{(\# \text{ of pharmaceutical industry clients declared in the EU Register})}{\# \text{ of clients the firm declared in the EU Register}} \times \frac{\text{total \# of staff declared in the EU Register}}{\text{in the EU Register}}$$

Finally, the estimated number of consultants serving pharmaceutical industry clients per firm was summed to arrive at an estimated total number of hired lobbyists representing the pharmaceutical industry in EU affairs.

Civil society organisations

Number: Nine civil society organisations were included according to the selection criteria in Annex B.

⁷² This calculation is based on data that is valid on 31 January 2012. It does not reflect subsequent changes to the EU Transparency Register.

⁷³ This figure is valid on 31 January 2012. It does not reflect subsequent changes to the EU Transparency Register.

Value: Sum of amounts spent on interest representation by each of the nine organisations.

Manpower: Not possible to determine.

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