Policy prescriptions

the firepower of the EU pharmaceutical lobby and implications for public health

CEO

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Erratum: The infographic on p. 11 was updated on 04/09/2015 to correct an error.

Disclaimer: The data from the European Parliament and the European Commission's Joint Transparency Register in this report is only a snapshot based on the Transparency Register on the specific dates the research was carried out (unless otherwise stated, companies 04/04/15, trade associations 11/04/15, consultancies 13/04/15, civil society 01/07/15 – for more details, see methodology in annex, and endnotes). As the data in the Transparency Register is changing constantly, with some entries updated on any given day, organisations' entries may have changed (or previously absent organisations signed up) since the dates this research was done. This report only reflects the information available in the Transparency Register on the dates specified, and any subsequent changes or additions to the Transparency Register are not accounted for. Data may be subject to omissions resulting from the Transparency Register's own search engine, as well as reasonable human error or omission.

Executive summary

The pharmaceutical industry – including companies, associations and the top ten lobby firms they employ – have a declared lobby spend of nearly €40 million. That is around 15 times more than the lobby expenditure of civil society and consumer groups which work on public health or access to medicines. Although many pharma industry actors declare more realistic expenditure in the lobby register than three years ago, the real spending may be much more. Nonetheless, the top ten biggest spending pharmaceutical companies now declare €6 million more than in 2012, whilst the top eight European pharmaceutical industry trade associations declare seven times more. Moreover this powerful lobby has had a staggering number of meetings with European Commission departments and officials. The largest public-private partnership in the EU is with the pharmaceutical industry. Alongside its gargantuan resources and considerable access, the industry has an impressive lobbying arsenal. Its efforts are now focused on ensuring US-EU trade agreement TTIP furthers its profit-motivated agenda, including its property rights and to prevent vital data transparency for big pharma's clinical trials.

Introduction

This report exposes the excessive lobbying influence of the pharmaceutical industry on EU decision-making. Big pharma enjoys semi-systematic privileged access to decision-making in Brussels, facilitated by its vast lobby expenditure, complex web of actors, extensive meetings with policy-makers, and participation in advisory groups.

The many channels of influence that the pharmaceutical industry uses, as well the EU laws and policies impacted by this, must be considered against the background of a flawed and industry-captured pharmaceuticals model, including the paradigm of the research, development, and regulatory approval of medicines.

In March 2012, Corporate Europe Observatory (CEO) and Health Action International – Europe (HAI Europe) published the report 'Divide & Conquer: A look behind the scenes of the EU pharmaceutical industry lobby'.[1] The report presented the lobby expenditure of pharmaceutical companies, trade associations, and the lobby consultancies that they employ, as well as showcasing some of the industry's influence strategies. This new report provides an update to, and builds upon, the picture of pharmaceutical lobby spending as it appears in the EU's Transparency Register. It also goes deeper into identifying big pharma's channels of influence in the EU and exposing concrete examples of EU law and policies that have been and are being impacted upon. For example, rules around clinical trials' data transparency, trade secrets, and the negotiation of the EU-US trade deal the Transatlantic Trade and Investment Partnership (TTIP).

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Section one of this report offers critical context to the pharmaceutical industry's extensive EU lobbying.

Section two reveals the lobby expenditure and lobby meetings of pharmaceutical companies, trade associations and the lobby consultancies they employ, as well as pharma's role in the Commission's advisory groups.

Section three puts the EU's major pharmaceutical industry trade association the European Federation of Pharmaceutical Industries and Associations (EFPIA) in the spotlight, examining its goals, tactics, access and influence, including a critique of the EU's multi-billion euro public-private partnership with EFPIA, the 'Innovative Medicines Initiative'.

Section four looks at the pharma industry's TTIP wishlist, and exposes its extensive lobbying – both under the Barroso II and Juncker Comissions – around the US-EU trade deal negotiations, including on intellectual property and clinical trials' data transparency.

1. Speaking 'Pharmish': the industry paradigm

The pharma lobby's influence at EU-level, both in ongoing debates and upcoming legislation, risks "an ever closer incestuous cooperation between the regulator and the regulated where any independent scrutiny of new medicines and their prices could be seriously weakened," according to Yannis Natsis from civil society consumer association the TransAtlantic Consumer Dialogue (TACD).[2]

The pharmaceutical industry is essentially attempting to ease the drug development pathway from research and development of a medicine through to clinical trials and market approval, in order to help its business model. This threatens the public interest, on questions of affordability, access, development of medicine for 'unprofitable' health problems, safety, and transparency of scientific data to name just a few.

In order to achieve its aims, big pharma uses sophisticated lobbying and public relations methods; as TACD says, "shaping the agenda by choosing its facts and promoting a language that is easily owned by everyone."[3] The industry has been very successful at framing "its profit-making goals as a proxy for public health objectives" by capturing and manipulating language in ways expertly designed to manipulate public understanding. To take just a few examples, this is done through the omnipresent use of terms like "innovation" (though the industry itself develops little that is meaningfully "new"), "research-based industry" (though in fact, most medicines research happens at universities funded by taxpayers), and "intellectual property rights" (which in fact are not rights, but rather, monopoly privileges granted by governments, and drive up prices).[4]

David Hammerstein from TACD describes this language as 'Pharmish', a form of doublespeak in which "'access' is not accessible, 'transparency' is not transparent and 'affordability' is not affordable".[5]

Many 'pharmish' phrases can be found in industry lobbying materials, examples of which are covered in this report. A worrying symptom of the industry capture of the debate, however, is the way that they have increasingly crept into the EU institutions' rhetoric as well. The concern is that this type of obscurantist language will be echoed in EU policy. For example, when the industry refers to "access to medicines" it doesn't in fact mean patients' access, but its own ability to get supposedly "innovative medicines" on the market.

There are two things which should be understood here. Firstly, facilitating market access in pharmaceutical industry terms means, in reality, shortening and simplifying so-called "regulatory barriers" – ie less stringent regulation and authorization procedures on the safety and efficacy of medicines, as well as less transparency about it.

Secondly, the industry's prolific use of the terms "innovation" and "innovative medicines" are misleading, for they do not necessarily refer to a drug which does something new or treats something differently, but simply to any new medicine on the market, even if this new or "innovative" medicine has no therapeutic added value compared to existing medicines. Thus "innovation" comes to mean selling new drugs rather than discovering and producing new treatments.

Additionally, using the term 'innovation' in this way enables the industry to argue that "more innovation" is served by greater intellectual property rights (IPR) protections, more patents, greater market access for its 'new' products and more restrictions for generic medicines (which are, of course, less profitable for industry), and, as noted above, weakening the regulatory "barriers" that are crucial to safeguarding public health.[6]

At a conference in November 2013, entitled 'Unblinding the public: Changing the narrative on pharmaceutical drug development, accountability and global health' and convened by Open Society Foundation's Access to Essential Medicines Initiative (AEMI), the problems with the big pharma paradigm were explored by health activists, corporate responsibility advocates, doctors, and academics. A picture emerged of how "the pharmaceutical industry exerts significant influence on law and regulations, marketing approaches, the behavior of doctors, academics,

patient groups and journalists. Its public relations efforts successfully reinforce its dominant position at the expense of global health."[7]

Problems with the pharma industry's profit-driven model are numerous. They include the irrational use and overuse of medicines, stemming from pharmaceutical industry incentives to doctors to prescribe particular medicines, as well as costly marketing campaigns pushing patients and patient groups to demand specific medicines.

As this report demonstrates, another major problem is the compromised integrity of the regulatory system, including the fact that the industry conducts its own clinical trials and owns and restricts access to the resulting data (see Box 5). A major part of this picture at the European regulatory level – which will be the subject of an upcoming briefing – is the pharmaceutical industry's influence over the European Medicines Agency, including a permissive conflict of interest policy and industry-funded patients groups.

One of the biggest reasons for public approval and political heft of the pharmaceutical sector is the argument that it funds research which improves our health and saves lives. Yet in reality, this argument is somewhat disingenuous; a significant proportion of pharmaceutical research is actually done by universities and/or funded by public money,[8] not by pharmaceutical companies, who more often develop a drug after buying its rights from the university or research institution.

Thus, whilst taxpayers fund university-based pharmaceutical research, patients are then effectively asked to fund these same "research" costs again by big pharma, who claim that high medicine prices and draconian IPR protections are necessary to maintain the incentive and resources for research and development (R&D). This – unsurprisingly – is a reality "that Pharma has worked tirelessly over the years to keep 'under wraps'",[9] although it remains difficult to get hold of comprehensive numbers showing the extent of this industry coup.

By successfully creating and propagating this dominant narrative, big pharma has convinced the public and policy makers that the medicines we need can only be successfully produced in the current model, one which depends on IPR monopolies and related high medicine prices to finance needed R&D. This is despite the fact that its profit-driven paradigm results in effective medicines being unaffordable for most of the world, whilst much-needed medicines remain undeveloped because they are not profitable.[10] Indeed, the World Health Organization (WHO) has unambiguously concluded that IPR are irrelevant for stimulating innovation in the absence of a profitable market, as in the case with diseases affecting millions of poor people in developing countries.[11]

Furthermore, the European Commission itself, in its 2008 Inquiry into the pharmaceutical sector, concluded that the balance between providing incentives for innovation and guaranteeing affordability to health products has been lost.[12] This inquiry revealed that pharmaceutical companies structurally abuse IPR, limiting generic competition, hurting innovation and costing European health systems billions. Their strategies include excessive use of litigation, patent clusters, practices like patent settlements, making misleading claims about inferior quality of generics in decisions on product authorisation and pricing and reimbursement status, and launching follow-on products to displace cheaper generic medicines based on the original product.[13] As a final point, IPRs are not rights at all, but rather serve as monopoly privileges, which limit the availability of low cost generic medicines and consequently hamper the goal of access to essential medicines for all.[14]

Critiques of the pharmaceutical industry model, such as Ben Goldacre's *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients* and Peter Gøtzsche's *Deadly Medicines and Organised Crime: How Big Pharma Has Corrupted Healthcare*, have provided greater public awareness of the disconnect between industry's glowing self-referential rhetoric and the realities of a model which fails public health goals whilst lining companies' pockets with billions. Gøtzsche's revelations that prescription drugs are the third leading cause of death after heart disease and cancer, provide the background to the fact that doctors have very little information about medicines that hasn't "been carefully concocted and dressed up by the drug industry". One of the major causes of this is "impotent drug regulation in need of radical reforms".[15]

Ben Goldacre similarly argues that "the whole edifice of medicine is broken", because the evidence upon which decisions about medicines are made is "hopelessly and systematically distorted" by the pharmaceutical industry:

> We like to imagine that medicine is based on evidence, and the results of fair tests. In reality, those tests are often profoundly flawed. We like to imagine that doctors are familiar with the research literature, when in reality much of it is hidden from them by drug companies.... We like to imagine that regulators only let effective drugs onto the market, when in reality they approve hopeless drugs, with data on side effects casually withheld from doctors and patients.[16]

Clinical trials – studies to determine the safety and efficacy of a medicine – are designed and carried out by the companies seeking to profit from the drug they're testing. They are often flawed by design "in such a way that they

Big pharma's profit-driven paradigm results in effective medicines being unaffordable for most of the world, whilst much-needed medicines remain undeveloped because they are not profitable

exaggerate the benefits of treatments... [and] tend to produce results that favour the manufacturer".[17] Even more problematically, when trials produce results companies don't like, "they are perfectly entitled to hide them from doctors and patients", with regulators playing a complicit role in protecting this data.

One such illustration is given by recent media coverage of Merck's birth control device NuvaRing, side effects from which can include blood clots and heart attacks[18] – so-called "acceptable risk factors" – which have been linked in a US class action to the deaths of 83 women, amid allegations of inadequately disclosed dangers of the device.[19]

The intense and multi-angled industry lobbying on clinical trial transparency revealed in this report – including for "commercial confidentiality" provisions to be applied at the discretion of pharma companies – must be considered in context. This context is that the harm that can come from a regulatory approval system which allows drug companies to control information about, and repress risks and dangers from, medicines and pharmaceutical products has a real-life high price.

BOX 1

Pharmaceutical lobby on trade secrets and intellectual property

According to *Spiegel Online*, a "record number of patents are set to expire in the next few years. A large number of cost-effective successor drugs will replace so-called blockbusters, which, according to Forbes, have made the pharmaceutical industry the world's most profitable sector."[20] Thus, the stakes for the pharma industry to protect, entrench and expand its intellectual property rights (IPR)-dependent business model are extremely high.

Trade deals may offer a way to help big pharma protect and expand this profitable IPR regime. In the EU, trade secrets are not classified as intellectual property rights (IPRs), because unlike patents, they do not form part of a social contract ie where governments grant a temporary monopoly in exchange for the publication of an invention.[21] Yet faced with increasing pressure for transparency around clinical trials results – which the industry fears would harm its commercial interests, both by giving data to competitors and by greater scrutiny over the actual trial results and the risks and benefits of a drug – big pharma seeks to effectively expand the scope of IPR protections to include the much more vague notion of "trade secrets".

When the Commission published a proposal for a trade secrets directive in November 2013, which includes aspects of the clinical development of drugs, major EU pharma lobby group EFPIA (European Federation of Pharmaceutical Industries and Associations) welcomed it with open arms. Given EFPIA's many Commission lobby meetings, prominence in expert groups, etc (see section 3) it may even have had a hand in shaping it. EFPIA justified the need for the directive by stating that the technical information and know-how created in the drug development process "can be of substantial economic value for our member companies... [and must be] protected from misappropriation".[22] Since the unveiling of the trade secrets proposal, EFPIA has also utilised the protection of trade secrets argument to fight against clinical trial data transparency, both as practised by EMA, and by means of the TTIP negotiations. The trade secrets directive itself is now being deliberated in the European Parliament, and many civil society groups, including Corporate Europe Observatory (CEO), are advocating for regulatory data of public interest to be explicitly excluded from the definition of "trade secret".[23]

However, as well as pushing for an expansion of IPR-type protections to cover "trade secrets" and clinical trial data, EFPIA also lobbies the EU to "insist on respect for IP globally".[24] It downplays the extent that IPRs act as monopoly privileges to pharmaceutical companies which hamper access to medicines in the global south, by arguing that "lack of access to medicines is rarely the consequence of a single factor".[25] This argument glosses over the very major "factor" of the inability of the poor to pay for expensive patented drugs, and consequently the lack of profit-motive for research into medicines that primarily affect the poor. EFPIA however demands that the EU "ensure affordable access to medicines without undermining the incentives needed for continued pharmaceutical research"[26] ie without undermining its lucrative IPR regime.

2. Pharmaceutical industry firepower: Lobby expenditure, meetings and expertise

The number of pharmaceutical industry actors – companies, trade associations and top lobby consultancies with big pharma clients – in the EU's lobby register has increased over the last few years. And in many cases, organisations' declared EU lobby expenditures have increased to more realistic levels. In part, this may reflect some progress towards more accurate and representative lobby disclosure, often as a result of scrutiny and pressure from civil society actors concerning under-reporting or misleading data in the Transparency Register. The steadily increasing numbers of signatories to the EU's lobby register can contribute to higher lobby spending totals, perhaps a sign that the reputational damage of continuing to lobby in the shadows is being taken more seriously, but also following the Juncker Commission's commitment to only meeting registered lobbyists. However, increased declared lobby spending by some actors may also reflect greater lobby activity around the EU-US trade agreement TTIP negotiations (see section 4).

Nonetheless, the data in the register must still be treated with caution: under-reporting remains a structural problem, and the register's voluntary nature and lack of effective monitoring suggests that overall industry spending is likely to be well over the €40 million revealed by the register. It is also worth noting that whilst entries in the lobby register do not all use the same reference year for financial data, the majority refer to 2014. This was an election year and a year of transition to a new European Commission team ie the European Parliament and Commission were not active with legislation for a significant part (perhaps one third) of the year. Thus it is reasonable to assume that lobbying activity – and expenditure – may have been less than in other years.

EU lobby expenditure by the pharmaceutical industry dramatically dwarfs the lobby resources of civil society actors working on public health or medicines issues

Finally, the data in the lobby register is changing constantly, with some entries updated on any given day. The data in this report is therefore only a snapshot based on the Transparency Register on the specific dates the research was carried out (unless otherwise stated, companies 04/04/15, trade associations 11/04/15, consultancies 13/04/15, civil society 01/07/15 – for more details, see methodology in annex, and endnotes). As such, it should be understood that organisations' entries may have changed (or previously absent organisations signed up) since the dates this research was done, and this report only reflects the information available in the Transparency Register on the dates specified.

BOX 2

How does big pharma lobby spending contrast with public health civil society expenditure?

EU lobby expenditure by the pharmaceutical industry dramatically dwarfs the lobby resources of civil society actors working on public health or medicines issues. The lobby power of pharmaceutical companies listed in the Transparency Register totals €22.9 million, pharma trade associations declare a combined spend of nearly €7.7 million, and the ten lobby firms spending the most on behalf of pharma clients have a revenue of €8.1 million from big pharma (see below). This totals just under €40 million (as of April 2015), nearly 15 times more than civil society groups working on public health and access to medicines spend.

The eight civil society organisations identified in the lobby register as working on access to medicines/public health issues at EU level – including consumer organisations and NGOs which also work on many other topics – declare a combined maximum lobby expenditure of just over €2.7 million (as of 1 July 2015).[27] This civil society total is just over a tenth of what pharma companies spend, and a third of what lobby consultancies receive from big pharma to lobby on its behalf. The combined fire power of the public health/consumer lobby on pharma issues totals about the same as a single EFPIA member company, chemical-pharmaceutical firm Bayer.[28]

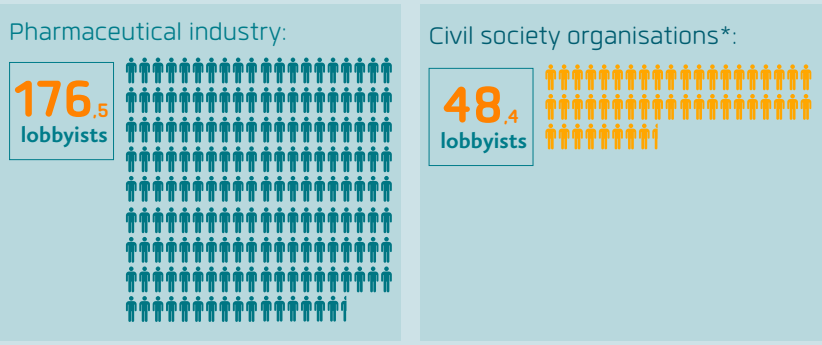
These civil society organisations have a total 48.4 full-time equivalent (FTE) lobbyists, with 44.5 European Parliament access passes. In contrast, the pharmaceutical companies and trade associations in the lobby register together declare a combined 176.5 FTE lobbyists – more than three times as many – with around 113 Parliamentary passes.[29]

See methodology in annex for more details on how industry and civil society actors were identified.

FIREPOWER OF BIG PHARMA LOBBY SPEND VS CIVIL SOCIETY

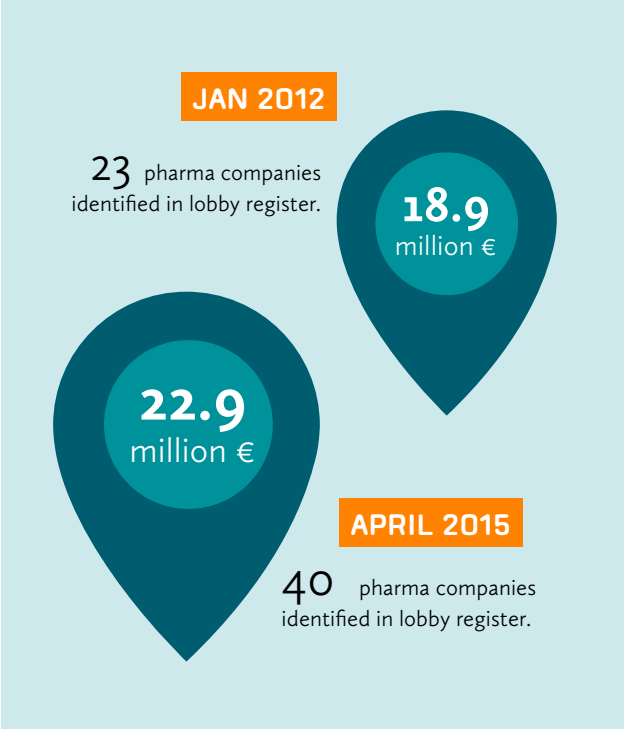
*Pharmaceutical companies and trade associations, plus the ten lobby firms earning the most from pharmaceutical industry clients, as of 4-13 April 2015 (see methodology in annex for exact dates)
** 8 civil society organisations identified in the Transparency Register as working on access to medicines / public health issues at EU level, including consumer organisations and NGOs which also work on other issues, as of 1 July 2015 (see methodology)

LOBBYISTS WORKING ON PHARMACEUTICAL ISSUES



*May also work on other issues

PHARMA COMPANIES DECLARED SPEND IN THE REGISTER

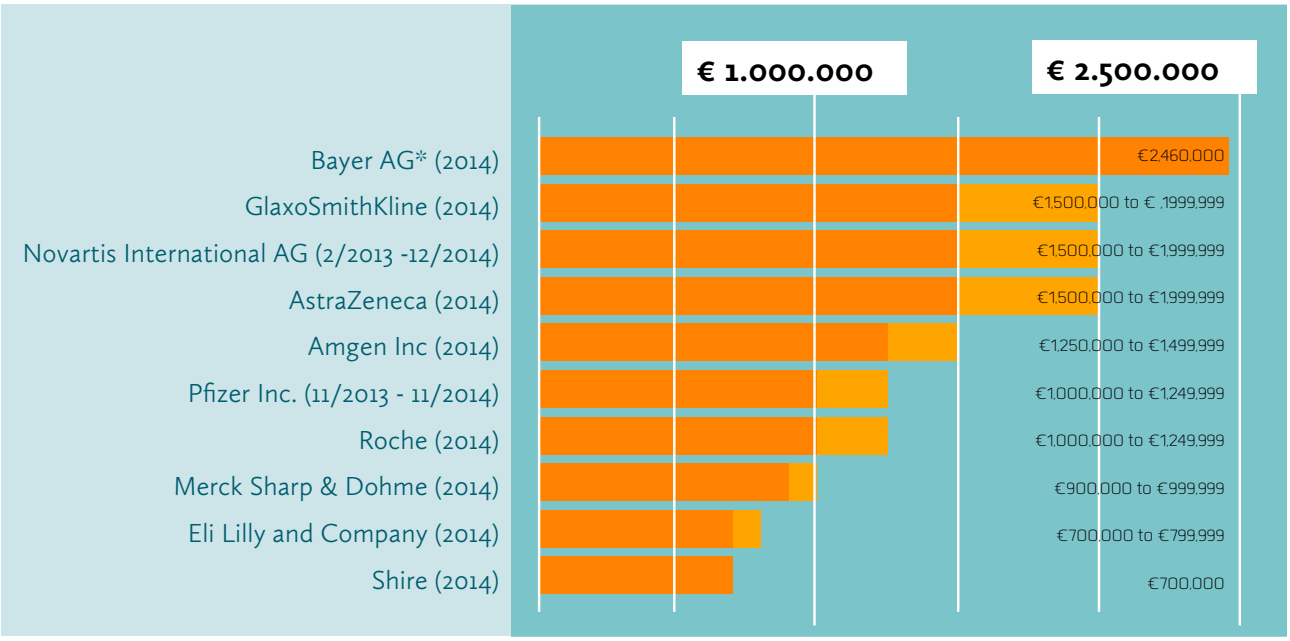


2.1. Pharmaceutical companies

Since CEO and HAI-Europe published the 2012 report 'Divide & Conquer: A look behind the scenes of the EU pharmaceutical industry',[30] the lobby expenditure declared by many pharmaceutical companies signed up to the still-voluntary Transparency Register for interest representatives – better known as the lobby register – has increased dramatically. In 2012, the top ten biggest spending pharmaceutical companies declared a combined EU lobby expenditure of a maximum €8.3 million – 3 years later, the register reveals that the now top 10 biggest spenders declare an estimated maximum of just under €15 million (as of 04/04/15) – nearly €6.6 million more.[31] These top 10 company spenders together have a total of 49 full-time equivalent lobbyists, 30 of those with access passes to the European Parliament.

A total of 40 pharmaceutical companies were identified (as of 04/04/15) in the lobby register (up from 23 in January 2012), declaring a total maximum expenditure of approximately €22.9 million (up from €18.9 million). The combined number of accredited lobbyists – ie those with access passes to the European Parliament – for the 40

TOP 10 BIGGEST PHARMACEUTICAL COMPANY SPENDERS IN TRANSPARENCY REGISTER



Total (MIN):	Total (MAX):	Total (AVERAGE):
€ 12.510.000	€ 14.959.992	€ 13.684.996,5

The figures in this table are based on the Transparency Register entries of the firms listed, as of 04/04/15. Lighter orange section of the bar indicates the bandwidth between minimum and maximum declared expenditure, where this is provided in register entries. For more details on methodology of identifying pharmaceutical companies in the TR, see appendix.
* It should be noted that Bayer also lobbies on issues besides pharmaceuticals, including pesticides and other chemicals. Bayer is included in the list of top spending pharma companies because it is a corporate member of EU pharmaceutical trade association EFPIA – see the methodology in the annex for more details on how pharma companies were identified. NB. The limited disclosure requirements of the Transparency Register do not enable us to see how much was spent lobbying on which law/issue – unlike, for example, the US lobby register. However, the inclusion of Bayer's full lobby expenditure should not skew the results, as the same has been done on the civil society side: e.g. consumer organisation BEUC also lobbies on many non-pharma issues, but this report counts BEUC's full expenditure and numbers of lobbyists as part of civil society's lobby spend on access to medicines/public health issues.

pharma companies identified in the register as of 4 April 2015 is around 89, whilst the total number of full time equivalent lobbyists is 108.

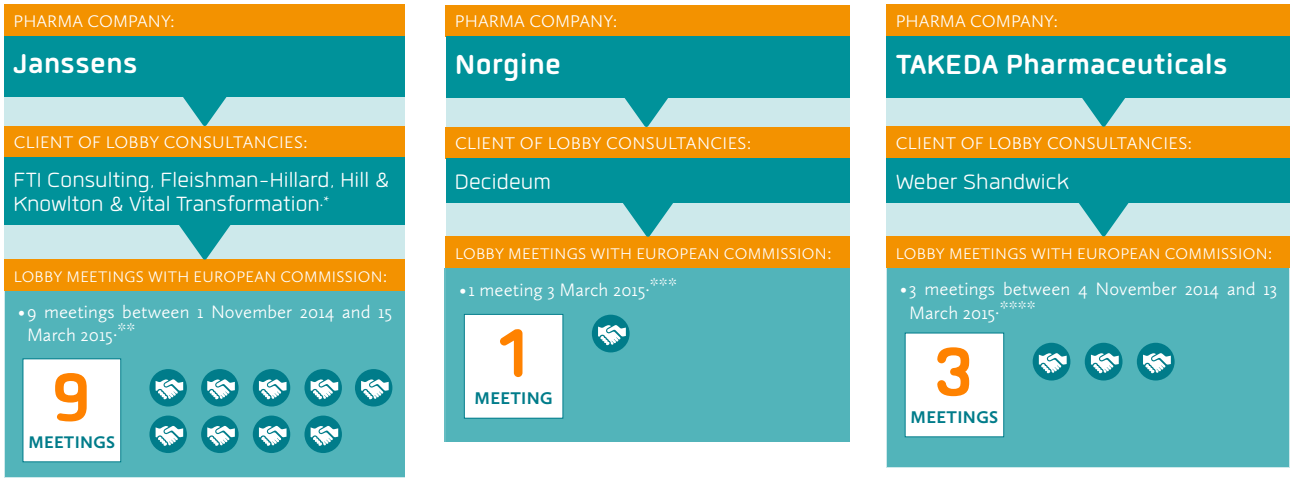
Interestingly, there are at least two pharmaceutical companies that, according to the Transparency Register, pay more to lobby consultancies than they declare as their total lobby expenditures in their own entries. **Alexion Pharmaceuticals** declares spending less than €9,999 on EU lobbying 01/2014 – 11/2014, but is listed as a client paying €25,000 to €49,999 to gplus in 2014.[32] **Stallergenes**, which declares lobby expenditure of €50,000 to €99,999 in 2014, is listed as a 2014 client of FTI Consulting Belgium, paying them €100,000 to €199,999.[33]

Many of the pharmaceutical companies signed up to the lobby register are also listed as clients of one or more lobby consultancies (see section 2.3). For example, the third biggest spender **Novartis** is listed as a client of no less than 11 different lobby consultancies: APCO Worldwide, Edelman Public Relations Worldwide, FIPRA International Limited, FTI Consulting Belgium, Fleishman-Hillard, Hill & Knowlton International Belgium, Instinctif Partners, Interel European Affairs, Rohde Public Policy, Teneo Strategy and acumen public affairs.[34] **Johnson & Johnson** is named as a client of five lobby firms,[35] as is **Sanofi**, the 11th biggest spender (€600,000 to €699,999 in 2014).[36]

There are also a number of pharmaceutical firms that are named as clients of lobby firms but which have failed to sign up to the register.

Astellas and Chiesi Farmaceutici SPA are also listed as clients of lobby firms but not signed up to the register (as of 13/05/15),[37] and there are a further number of companies which – as full corporate members of EFPIA, the pharmaceutical industry's main EU lobby group – are clearly interested in influencing EU decisions, but are absent from the lobby register. These include **Menarini**, **Orion Pharma**, **Almirall**, **Boehringer Ingelheim**, and **Daiichi Sankyo (as of 04/04/15)** – the latter three have all had meetings with the European Commission (see Section 3). Thus, it is clear that there continue to be pharmaceutical companies lobbying the EU that shun transparency, despite paying lobby firms to act on their behalf, being members of lobby groups, or meeting directly with EU institutions (see Section 2). It also demonstrates that the Commission continues to meet with unregistered pharmaceutical lobbies.

EXAMPLES OF PHARMACEUTICAL FIRMS NOT IN REGISTER, BUT NAMED AS LOBBY FIRM CLIENTS:



* Based on the TR entries of these firms, as of 13/05/15. This infographic was corrected on 04/09/15 as it contained an error, mistakenly naming Norgine as a client of Weber Shandwick and Takeda as a client of Decideum, when in fact this is the other way around. (Norgine is still listed as a client of Decideum (11/2013 - 10/2014) and Takeda as a client of Weber Shandwick (2014) in their Transparency Register entries, as of 04/09/15)."

** Janssen has had lobby meetings with the Juncker Commission, including with Directorate General for Health and Food safety (DG SANTE) on 24 November 2014, and eight meetings with Directorate General for Research and Innovation (DG RTD)'s Health Directorate between 1 November 2014 and 15 March 2015.
Based on documents released following requests by Rachel Tansey under EU Access to Documents laws (Regulation (EC) No 1049/2001), to DG SANTE (GestDem 2015/1729 – documents received 15/04/15) and to DG RTD (GestDem 2015/1628 – documents received 06/05/15, released under code of good administrative behaviour).

*** Norgine met with DG GROW's Health Technology and Cosmetics Unit on 03 March 2015. A2D request to DG GROW, ibid.

**** TAKEDA Pharmaceuticals met with DG RTD's Health directorate 12-13 March 2015 (on the subject of EU Research & Innovation), with Directorate General for Internal Market, Industry, Entrepreneurship (DG GROW – formerly known as DG ENTR) Unit on Food and Healthcare industries and Biotechnology on 4 November 2014, and with DG SANTE's Healthcare Systems unit on 9 March 2015.
Based on documents released under EU Access to Documents laws (Regulation (EC) No 1049/2001) to Rachel Tansey, by DG GROW (Ref GestDem 2015/1652 – documents received 30/04/15), by DG RTD and DG SANTE, ibid.

Pharma companies comfortably accommodated by the Commission: Access to documents requests, together with the European Commission's online disclosure, have revealed a staggering number of meetings between pharmaceutical companies and Commission departments that are involved in EU-level policies or projects that are of direct commercial concern to the companies themselves. For example, between the start of the Juncker Commission's office on 1 November 2014 and mid-March 2015:

PHARMA COMPANIES-EU COMMISSION MEETINGS:

GlaxoSmithKline

- DG GROW: December 2014
- DG RTD's Health directorate: four times in November and twice in December 2014, five times in January, once in February and twice in the first half of March 2015. [38]

15 MEETINGS

Novartis

- DG GROW: November 2014
- GROW's Director-General Daniel Calleja Crespo: March 2015
- DG RTD's Health directorate: November 2014, January and March 2015
- DG SANTE's Medicinal products, authorisations and EMA unit: twice in November 2014
- DG SANTE's Healthcare systems unit: February 2015. [39]

8 MEETINGS

Johnson & Johnson

- DG SANTE's Health systems and products unit: February 2015
- DG RTD's Health directorate: November and December 2014, twice in January and once in February and the first half of March 2015 [40]

6 MEETINGS

Sanofi

- GROW Commissioner Bieńkowska's cabinet: January 2015
- DG SANTE's Strategy and international unit: November 2014
- DG RTD's Health directorate: November and December 2014, plus in February and March 2015. [41]

6 MEETINGS

Pfizer

- GROW Commissioner Bieńkowska's cabinet: January 2015
- SANTE Commissioner Vytenis Andriukaitis: March 2015
- DG TRADE: February 2015
- DG RTD Health Directorate: February and March 2015. [42]

5 MEETINGS

Eli Lilly

- GROW Commissioner Bieńkowska's cabinet: January 2015
- SANTE Commissioner Andriukaitis' cabinet: February and March 2015
- DG RTD Health directorate: Nov 2014 and Jan 2015. [43]

5 MEETINGS

Novozes

- DG GROW: November 2014
- First Vice-President Frans Timmermans' cabinet: March 2015
- TRADE Commissioner Cecilia Malmström's cabinet: February 2015 [44]

3 MEETINGS

Celgene

- DG GROW: November 2014
- SANTE Commissioner Andriukaitis: February 2015 [45]

2 MEETINGS

Novo Nordisk

- DG SANTE's Programme Management and Diseases unit: March 2015
- DG RTD's Health directorat: November 2014 [46]

2 MEETINGS

BOX 3:

Behind the scenes: organisations funded by big pharma

There are more covert ways that the pharma industry may exercise influence through the funding of groups which do not appear to be intended to promote its interests. For example, many patients' representative groups active at EU level are in fact significantly or even majority funded by the pharma industry.

There are other groups – which due to their pharmaceutical funding and promotion of industry interests – raise fears of acting, or risk being perceived as, pharmaceutical industry 'front groups'. Some examples of these crop up later in the report, such as the Alliance for Healthcare Competitiveness (see TTIP section). Some of the other lobby groups found in the EU's lobby register, which enjoy pharma funding or other pharma ties, are presented in Table 1.

TABLE 1: HEALTH ORGANISATIONS AND PATIENT GROUPS FUNDED BY BIG PHARMA

Name of group	EU Lobby expenditure declared	Notes	Lobby firms employed
European Kidney Health Alliance (EKHA)	€50,000 - €99,999 01/2014 to 11/2014.[47]	– €35,000 industry sponsorship of its annual event. – Secretariat of informal MEP Group on Kidney Health; appears to act as a kind of MEP-industry forum whose events are sponsored by big pharma.[48]	Interel European Affairs (2014); fee €100,000 – €199,999[49] – more than it declares in its own register entry.
European Respiratory Society (ERS)	€300,000 - €399,999 03/2013 – 02/2014.[50]	– Donors include many pharmaceutical firms eg Almirall, Astra Zenecca, Pfizer, GSK and Bayer.[51] – ERS President declares pharma fees of over €10,000 for consultancies / advisory boards, inc. GlaxoSmithKline, Novartis & Merck, plus many industry research grants.[52] – Vice President also declares fees from lectures and/ or advisory board memberships of pharma companies inc Astra Zeneca (€5,000 to €20,000) and Novartis (€1,000 to €5,000), & research grants from pharma companies, incl over €20,000 from GlaxoSmithKline.[53]	Weber Shandwick (2014)[54]
European Union Geriatric Medicine Society (EUGMS)	€25,000 - €49,999 for 2014.[55]	– Members incl Pfizer, Eli-Lilly, Astra Zeneca & Bayer. – No info on pharma funding in register entry; yet website reports EUGMS' current sponsors include Abbott, GlaxoSmithKline, Pfizer, Sanofi Pasteur MSharp & Dohme.[56]	Marking Public Affairs bvba[57]
European Academy of Allergy and Clinical Immunology (EAACI)	€100,000 - €199,999 for 2013. [58]	– No info on its pharma sponsors, but website lists "Founder sponsors" including Novartis, Stallergenes, & ThermoFisher Scientific.[59]	Interel European Affairs[60]

There are more covert ways that the pharma industry may exercise influence through the funding of groups which do not appear to be intended to promote its interests.

2.2. Pharmaceutical industry trade associations

Pharmaceutical industry trade associations are alliances of big companies, and those that are active at EU level have together dramatically increased their level of *reported* spending on lobbying by €5.4 million in the last three years.

At least 18 pharmaceutical industry trade associations – both pan-European and national – can be found in the Transparency Register, together spending a declared maximum of nearly €7.7 million representing their members interests at EU level (as of 11/04/15).[61] This is a big increase from 2012 figure, declared as a maximum of €2.3 million.[62] These 18 trade associations together currently declare 68.5 full time equivalent lobbyists, and have a combined 24 lobbyists accredited for passes to the European Parliament.

The 18 associations identified include the eight biggest spending European pharmaceutical industry trade associations that were identified in our 2012 Divide & Conquer report. Together, these eight European pharma associations now declare spending nearly seven times more than three years ago. Between them, they hold 14 Parliamentary access passes.

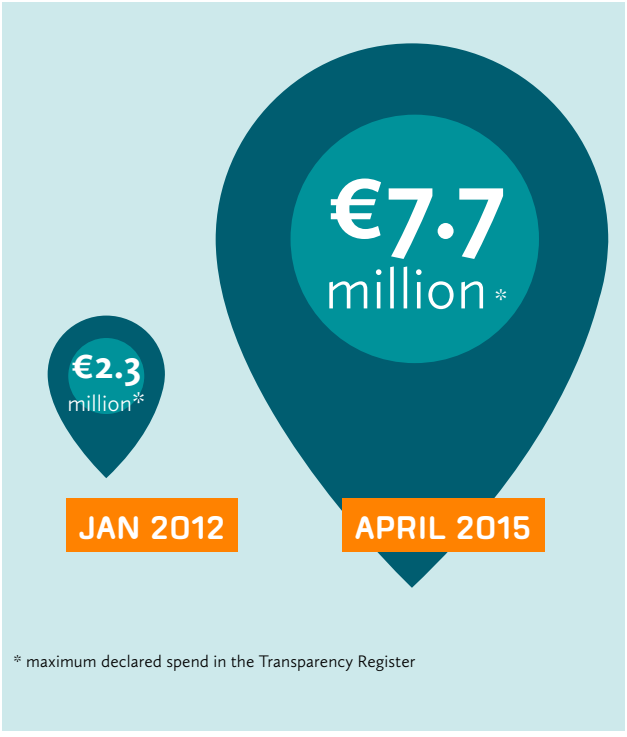
Some of the biggest pharma trade association spenders however are national (rather than European) associations. For example, for 2014, France's LEEM declares €200,000 to €299,999, Germany's VFA declares €250,000, and Belgium's pharma.be declares €225,000 on EU lobby expenditure (as of 11/04/15).

The United States' largest pharma industry body, Pharmaceutical Research and Manufacturers of America (PhRMA), continues to remain absent from EU lobby register, despite documented evidence of its lobbying at EU level. This includes considerable access to the European Commission, particularly on EU-US trade agreement TTIP (see Section 4).

Commission lobby meetings with pharma trade associations

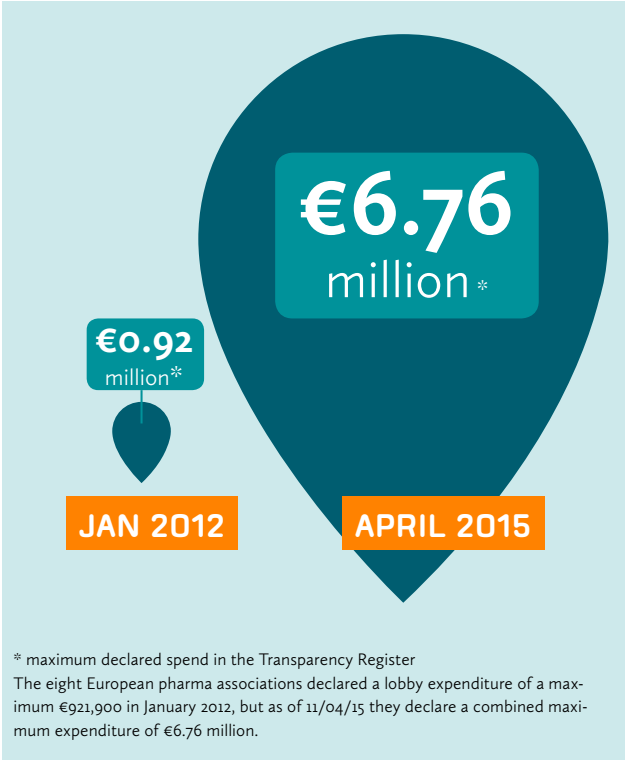
Access to documents requests have revealed that of all the pharma trade associations, EFPIA has had by far the most meetings – over 50 – with relevant Commission departments since the Juncker Commission started office on 1 November 2014 (to mid-March 2015). However, other pharma associations listed in the Transparency Register are also playing an active part meeting with the Juncker Commission:

PHARMA TRADE ASSOCATIONS SPEND INCREASE 2012-2015



* maximum declared spend in the Transparency Register

TOP 8 EUROPEAN PHARMA TRADE ASSOCIATIONS DECLARE 7 FOLD SPENDING INCREASE



* maximum declared spend in the Transparency Register
The eight European pharma associations declared a lobby expenditure of a maximum €921,900 in January 2012, but as of 11/04/15 they declare a combined maximum expenditure of €6.76 million.

COMMISSION LOBBY MEETINGS WITH PHARMA TRADE ASSOCIATIONS

European Association of Full-Line Wholesalers (GIRP)

- DG GROW: 1 in November/December 2014.
- DG SANCO: 3 times in November/December 2014 [63]

4 MEETINGS

European Self-Medication Industry (AESGP)

- DG SANTE: December 2014
- DG GROW: March 2015
- Cabinet of Commissioner for Internal Market, Industry, Entrepreneurship and SMEs: January 2015 [64]

3 MEETINGS

FARMINDUSTRIA (Italian pharma association, national member of EFPIA)

- DG SANTE: 1 in November, 1 in December 2014 [68]

1 MEETING

EUCOPE

- DG SANTE: 2 in November 2014, 2 in January 2015
- Commissioner for Health and Food Safety Vytenis Andriukaitis's cabinet: April 2015 [65]

5 MEETINGS

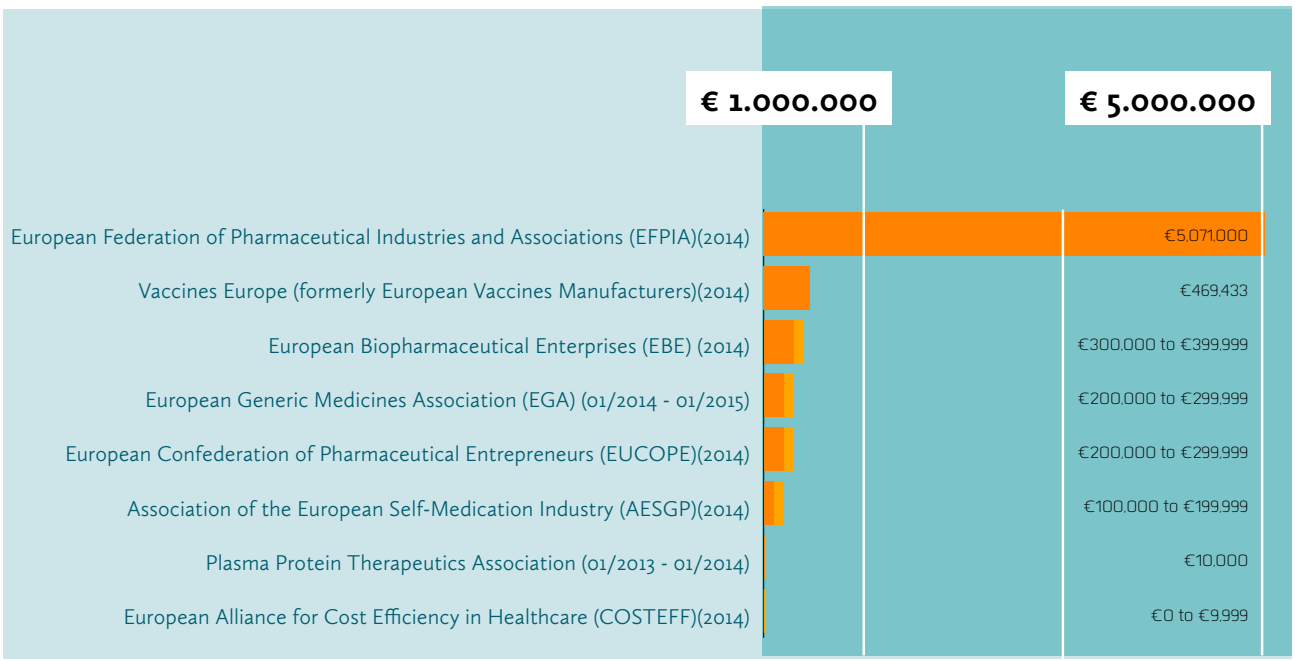
EGA

- DG SANTE: 6 meetings
- DG RTD: 1 meeting [66]
- Cabinets of 4 Commissioners (DG SANTE: 2 meetings, DG TRADE: 1 meeting, DG GROW: 1 meeting, DG RTD: 1 meeting) and the cabinet of Commission President Juncker: 1 meeting. [67]

13 MEETINGS

Other pharmaceutical trade associations, which have not signed up to the lobby register, have also been shown to be getting access to decision-makers in the Commission's DG SANTE, including EALTH (European Association for Logistics and transportation in healthcare) and APRaD (Association of Pharmaceutical Research and Development – see Section 3).[69]

TOP EIGHT EUROPEAN PHARMACEUTICAL TRADE ASSOCIATIONS



Total (MIN):	Total (MAX):	Total (AVERAGE):
€6350433	**€6760428**	**€6555430.5**

The figures in this table are based on the Transparency Register entries of the firms listed, as of 11/04/15. Lighter orange section of the bar indicates the bandwidth between minimum and maximum declared expenditure, where this is provided in register entries. For more details on methodology of identifying pharmaceutical trade associations in the TR, see appendix.

Box 4

Pharma industry shapes policy agenda in Expert Groups

Big pharma representatives appearing in expert groups have a role – both explicit and covert, such as pharma company representatives advising in a "personal capacity" – in shaping the policy agenda.

The corporate dominance of the European Commission's expert groups – whose advice helps make official policy for the EU – is a serious concern in the area of pharmaceuticals. Big pharma representatives appearing in expert groups have a role – both explicit and covert, such as pharma company representatives advising in a "personal capacity" – in shaping the policy agenda. According to the European Commission's register of expert groups European pharmaceutical lobby association EFPIA is currently a member of several active groups, including the European Alcohol and Health Forum, the Technical Expert Group for the implementation of the Directive on the protection of animals used for scientific purposes, and the Expert Group on Corporate Responsibility in the field of Pharmaceuticals.[70]

This latter's mission statement concerns ensuring that "pharmaceutical industry strategies are in line with the public health and societal needs" and "considering in a balanced approach societal and industrial challenges". Beyond the 28 national administration members (both EU and third country), the 16 other organisations include a significant number of pharma and related industry lobby groups. These include EFPIA, GIRP, AESGP, the European Generic medicines Association (EGA), bio-tech lobby EuropaBio, and the pharma-funded European Patients Forum (EPF), plus pharmacists association the Pharmaceutical Group of the European Union (PGEU). By contrast, there are no environmental NGO members, and only one consumer group member, BEUC.[71]

EFPIA is also represented in the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering.[72] This group's mission is to provide legal and technical expertise on highly controversial intellectual property law – including on life sciences and biotech – and to "provi de the Commission with analysis and position papers" on topics related to the Directive on the legal protection of biotechnological inventions. Its membership includes so-called individual experts appointed in their "personal capacity", as well as those appointed as representatives of an interest.

CEO has long criticised the appointment of experts in their personal capacity as an opaque way of allowing industry lobbyists to advise the Commission on areas of direct commercial interest to them. This group offers a clear example of this problematic practice – Gautier Pereira, one of nine "personal capacity" experts, who is listed only as a "Senior Manager Legal in the pharmaceutical industry", is, according to Pereira's Linked-in profile, an employee of pharma giant and self-declared lobby on IP issues, GlaxoSmithKline.[73] Its five experts representing an interest include "Ginger IP Consulting Limited advising EFPIA", as well as a patent attorney at biotech/biopharma firm Novozymes, on behalf of EuropaBio, the European biotech lobby.[74] EuropaBio's membership has considerable cross-over with EFPIA's, including Novartis, Pfizer, Bayer, GSK, Eli Lilly, and many more.[75]

Another example of pharmaceutical company lobbyists formally advising the Commission is the expert group on rare diseases.[76] The active group's list of members includes European Biopharmaceutical Enterprises (EBE – a specialised group of pharma trade association EFPIA) and EuropaBio. What it doesn't tell you is that the EuropaBio representative is actually from pharma giant GlaxoSmithKline, as revealed in GSK's Transparency Register entry.[77] Other members of the rare diseases expert group include the European Genetic Alliances' Network (EGAN), whose website lists its recent pharmaceutical sponsors as Genzyme, AMGEN, Novartis, and Roche. The European Organisation for Rare Disease (EURORDIS) is also a member, which got over a quarter of its revenue from pharma and biotech companies in 2013, its five largest donors being Celgene, Sigma Tau, GlaxoSmithKline, Shire and Genzyme.[78] EURORDIS also has a Round Table of Companies (ERTC), which it describes "a "club" of pharmaceutical companies with a common interest in rare diseases and orphan drug development".[79] 'Orphan' drugs, so named because the pharmaceutical industry has little interest under normal market conditions in developing and marketing drugs intended for only a small number of patients suffering from very rare conditions, receive various incentives under EU regulation – fee reductions, market exclusivity, research funding, and grants etc.[80] These are lucrative advantages for multi-billion euro pharmaceutical companies including AstraZeneca, Celgene, Pfizer, for whom EURORDIS' ERTC fees (they each pay €25,000 to be members) are a drop in the ocean. Especially in return for "constructive dialogue being developed between industry, patient organisations, as well as national and European authorities", which ERTC promises its members.[81]

The entrenched high level access and influence of big pharma is exemplified by these kinds of advisory group.

2.3. Lobby consultancies hired by the pharmaceutical industry

There are hundreds of lobby consultancies active in Brussels offering their services to companies and groups eager to have their interests represented in the inner EU policy-making circle. This is often aided by the many former EU officials who have gone through the revolving door to be employed by major lobby firms.[82] However, there is a smaller proportion of Brussels lobby firms that to some degree specialise in pharmaceuticals-related issues (medicines, healthcare, intellectual property, etc), and therefore have a cluster of pharmaceutical industry clients, be they companies, trade associations, or other representatives. According to the Transparency Register, there are at least 25 lobby consultancies with one or more pharmaceutical industry clients, 13 of these with four or more pharma clients (as of 13/04/15).[83] Five lobby consultancies declare having ten or more pharma clients: see infographic below. [84]

The top ten pharma-earning lobby firms now have a total revenue of an average of nearly €8.1 million from pharmaceutical clients – nearly €1 million more than three years ago (see page 21).

The lobby firms in the Transparency Register which name pharmaceutical companies as clients are, in effect, declaring the amount of money that those companies have paid them to undertake activities which fall under the Commission and Parliament's definition of interest representation. This definition includes activities "carried out with the objective of directly or indirectly influencing the formulation or implementation of policy and the decision-making processes of the EU institutions".[85] Interest

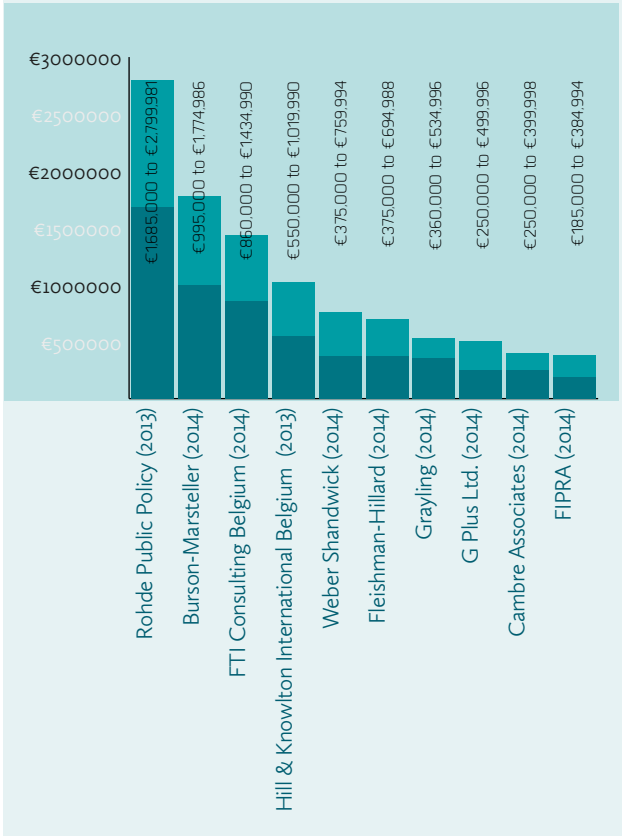
For more details on methodology of identifying consultancies with pharma clients in the TR, see appendix.

representation, or lobbying, is arguably at its most direct in the form of meetings with EU officials and policy-makers. The Juncker Commission has made a commitment that all its Commissioners, their cabinets and the Director Generals of the various Commission departments, must disclose online all meetings with stakeholders. But if the goal of lobby transparency is to provide the public with accurate information on who is lobbying who, on behalf of whom, for how much and on what topics, this practice only provides part of the picture when it comes to meetings with lobby consultancies.

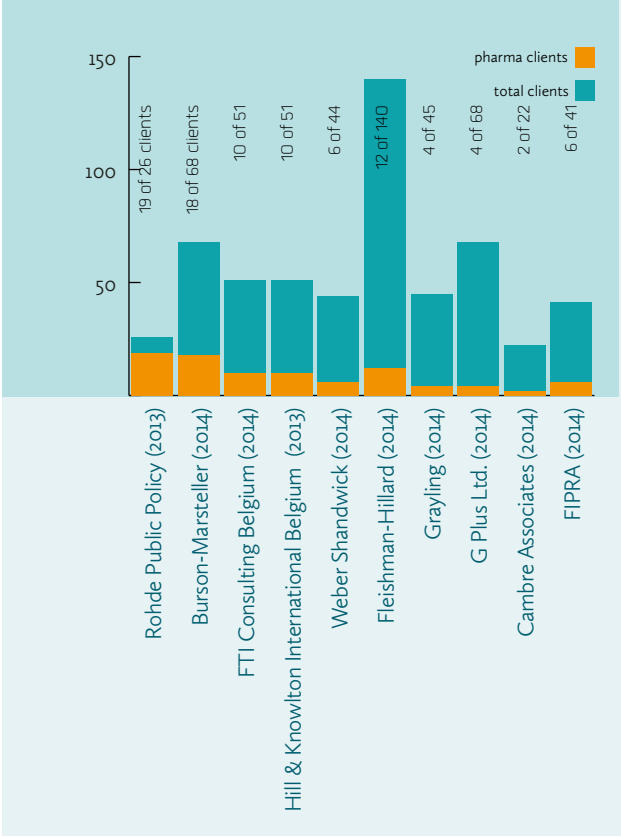
For example, DG GROW Commissioner Elżbieta Bieńkowska's cabinet declares meeting with lobby firm FIPRA International Limited in January 2015 concerning the life sciences sector – which includes medicines and related clinical issues.[86] But this information does not tell us on behalf of which client FIPRA – which has the 10th highest income from pharmaceutical clients of lobby firms in the register – was acting (and on which issue or law they lobbied for the client). According to the Transparency Register (as of 13/05/15), FIPRA's pharma clients include Sanofi, EFPIA, Merck Sharp & Dohme, Mylan, Pfizer, and Novartis, together bringing the lobby firm an average total of €284,997 in 2014.[87] Similarly, SANTE Commissioner Vytenis Andriukaitis' cabinet met with Hill and Knowlton (the fourth highest earner from pharma clients) regarding Immuno-oncology treatments in February 2015, but no information as to which client this lobby meeting was on behalf of is provided.[88] Hill and Knowlton's pharma clients listed in the lobby register include Shire, EPEMED, Chiesi, MSD Europe, Novartis, Pfizer, Amgen, GSK, Janssen and Lundbeck, bringing them an average of €784,995 in 2013.[89]

TOP 10 LOBBY FIRMS BY EARNINGS FROM PHARMACEUTICAL INDUSTRY CLIENTS

Pharmaceutical client revenue in €



No. pharma clients of total clients



Total (MIN) revenue:	Total (MAX) revenue:	Total (AVERAGE) revenue:
€5.885.000	**€10.304.913**	**€8.094.955,5**

The figures in this table are based on the Transparency Register entries of the firms listed, as of 13/04/15. For more details on methodology of identifying consultancies with pharma clients in the TR, see appendix.

Box 5

Clinical trials' data transparency

The issue of data transparency of big pharma's clinical trials is one that crops up repeatedly in industry lobbying, including around EU-US trade agreement TTIP. But in order to understand what's at stake and why this issue matters so much – both to the pharmaceutical industry, eager to protect its commercial interests, and to public health advocates, determined to ensure information on the risks and benefits of drugs can be accessed by the public – a little background is necessary.

What are clinical trials? Clinical trials are studies intended to discover or verify the effects of one or more investigational medicine (a drug in the testing phase which has not yet gained regulatory approval). The European Medicines Agency (EMA) – the EU agency responsible for the scientific evaluation of medicines developed by pharma companies in the EU – relies on the results of clinical trials carried out by pharmaceutical companies to reach its opinions on the authorisation of medicines.[90]

Why is clinical trial data transparency important? Public access to clinical trial data is crucial for the protection of public health. Only by disclosing the true effects of medicines (including risk levels and evidence of benefits) can doctors (those prescribing the medicine) and consumers (those taking it) make informed choices about treatment. It is also necessary to allow independent scientific assessment of data to ensure the safety and efficacy of medicines.[91]

What's the clinical trials story at EU level? There are several aspects to the clinical trials transparency story in the EU. In July 2012, the European Commission presented a proposal for a new regulation on clinical trials, intended to "make the European Union more attractive for clinical research". However, public health groups saw this as an opportunity to introduce transparency requirements for clinical trials data. Many such organisations pushed for the new regulation to place patients' interests before those of big pharma, and as a result the European Parliament improved the Commission's original proposals, including by introducing greater transparency requirements from companies regarding the results of their clinical trials. Member states' health ministers supported and reinforced these measures. The new Clinical Trials Regulation was adopted by the European Parliament in early April 2014, and will apply from mid-2016.

Despite this positive advance, clinical trial data transparency is threatened on several fronts, including a restrictive (and industry-influenced) approach being taken by EMA on publishing the data, a proposed directive on trade secrets published by the Commission in November 2013, and the influence of the pharmaceutical lobby in the TTIP negotiations (see Section 4), as a way to undermine this progress.[92]

You can find out more on the threat to clinical trial study data transparency from trade secrets laws and TTIP in Section 4, as well as about EFPIA's lobbying on clinical trials in Section 3.

3.Spotlight on EFPIA: Heart of the EU pharmaceutical lobbying machine

The European Federation of Pharmaceutical Industries and Associations (EFPIA) is the pharmaceutical industry's main EU lobby group and by far the biggest spender of all pharmaceutical trade associations. Its members include the biggest and most powerful pharmaceutical companies in the world, such as GlaxoSmithKline, Pfizer, Eli Lilly, Astra Zeneca, Baxter, Johnson & Johnson, Novartis, Shire, Sanofi, and Roche.[93] EFPIA enjoys an influential position in EU pharmaceutical-related policy making. This is indicated in part by the sheer number of meetings behind closed doors it holds with the European Commission (more than 50 held with DG SANTE, DG RTD, DG GROW and DG TRADE in the first four and a half months of the Juncker Commission), its multi-million euro lobby expenditure, and the many lobby consultancies it hires. It is also illustrated by the extent to which the profit-driven commercial interests of big pharma, softened by misleading rhetoric like "access to innovative medicines", have become part and parcel of the EU's policy-approach to pharmaceuticals. One particularly vivid example of this is the Commission-EFPIA multi-billion euro public-private-partnership IMI (Innovative Medicines Initiative, see section 3.3).

3.1. The pharmaceutical industry's European powerhouse

Multi-million budget: In its own Transparency Register entry (as of 11/04/15), EFPIA declares a lobby expenditure of over €5 million for 2014 (see chart on page 17, Top eight European pharmaceutical trade associations).[94] In our 2012 report, we noted that EFPIA declared a lobby expenditure of less than €50,000 in 2010, jumping to €571,900 in its declaration for 2011.[95] Increasing tenfold between 2010 and 2011, its declared EU lobby expenditure for 2014 has once again increased tenfold. EFPIA attributes this partly to changes in the register's guidelines, including an increasing range of activities that fall under the register's scope and changes in the way calculations for full time equivalents are made.[96] Given the extraordinary jump in declared expenditure - a one hundred fold increase in four years (<€50,000 in 2010 to >€5,000,000 in 2014) - EFPIA's explanation seems a little dubious. For although it is true that the register's guidelines *have* become more specific over time, the general instructions concerning what should be included as lobbying expenses were reasonably comprehensible before.

Army of lobby firms: EFPIA is listed as a client by six lobby consultancies in the register (as of 13/05/15). These include gplus Ltd (€100,000 to €199,999), Vital Transformation (€50,000 to €99,999), Burson Marsteller (€25,000 to €49,999), and FIPRA International Ltd (€10,000 to €24,9990) in 2014, and HCS sprl (below €9,999, but listed twice) and APCO Worldwide (below €9,999) in 2013.

EFPIA in expert groups: Despite its lobby register entry listing no information in the 'Participation in EU structures and platforms: Expert groups (European Commission)' section (as of 13/05/15), EFPIA is currently a member or represented on at least four active Commission expert groups, according to the Commission's own register of expert groups (see Box 4).

EFPIA's "specialised groups": Vaccines Europe and European Bio-Pharmaceutical Enterprises

EFPIA states in its Transparency Register entry that it has two specialised groups: Vaccines Europe (VE) and the European Bio-Pharmaceutical Enterprises (EBE). These groups are registered separately from EFPIA in the lobby register (though, as EFPIA states, they have no legal responsibility, but fall under EFPIA's). Thus, whilst VaccinesEurope and EBE are the second and third biggest pharma trade association spenders in the lobby register, respectively (see chart on page 17, Top eight European pharmaceutical trade associations), they are in fact specialised groups of EFPIA. Both VaccinesEurope and EBE have had lobby meetings with the European Commission. For example, VaccinesEurope met DG RTD in March 2015 and DG SANTE in January and February 2015. EBE met DG SANTE in February 2015,[97] and also sits in two Commission expert groups, on cancer and on rare diseases (see Box 4). EFPIA's tentacles thus reach further than it would first appear.

clinical trial data transparency is threatened on several fronts, including a restrictive (and industry-influenced) approach being taken by EMA on publishing the data, a proposed directive on trade secrets published by the Commission in November 2013, and the influence of the pharmaceutical lobby in the TTIP negotiations

Empty promises on transparency? In the financial data section of EFPIA's lobby register entry, it states that EFPIA recommends that "each of its constituent entities – including corporate members, member associations and members of specialised groups – register in their individual capacity". It also states that "Constituent entities that are not included in the EU "Transparency Register" shall not be part of EFPIA delegations interacting with the EU Commission / EP."

On its website, EFPIA lists 40 corporate members (34 full and 6 affiliate), as well as 33 national member associations (19 full and 14 affiliate).[98] Of its 40 corporate members, 14 are absent from the Transparency Register (as of 11 May 2015).[99] Only five of EFPIA's 33 member associations could be found in the register, the national pharma associations of Germany, France, Italy, Belgium, the UK, and Austria.[100]

The question is, does EFPIA's lobby register pledge that any members who've ignored its guidance to sign up to the Transparency Register will not take part in EFPIA meetings with the Commission or Parliament, hold up to scrutiny? According to the results of our access to documents requests for lists of meetings with pharmaceutical industry representatives held by various European Commission departments (since the Juncker Commission entered office on 1 November 2014 to mid-March 2015), it does not. For example, EFPIA full corporate members Almirall and Boehringer Ingelheim, and affiliate corporate member Vifor Pharma, all of which are absent from the lobby register, attended a meeting, together with EFPIA, with the European Commission's DG RTD's Health directorate, on 25 February 2015.[101] Furthermore, EFPIA had a meeting together with its unregistered Ukrainian national (affiliate) member association the Association of Pharmaceutical Research and Development (APRaD) with the Commission's DG SANTE on 16 March 2015.[102]

Perhaps EFPIA's failures to meet its own standards on transparency are less surprising when one considers its lobbying efforts to restrict transparency around access to documents, in the name of industry competitiveness.[103] In March 2014, EFPIA – together with biotech lobby Europabio and pesticides lobby the European Crop Protection Association (ECPA) – wrote to Commission Secretary-General Catherine Day to convey "strong concerns about the current implementation by EU agencies of the legislation dealing with public access to documents". Their concern about the the implementation of EU transparency legislation (Regulations 1049/2001 and 1367/2006 and Directive 2003/4) was based on "their likely effect on the competitiveness and attractiveness of the European Union as a place to do business for innovative companies, including many SMEs".[104] What is more worrying however is that Catherine Day did not dismiss this corporate plea to restrict the legally enshrined right of public access to documents but instead responded that the "European Commission shares your concern that a correct balance must be found between the two legal instruments".[105]

3.2. EFPIA lobby meetings with the European Commission

Documents released to CEO have revealed that between 1 November 2014, when the Juncker Commission's entered office, and mid-March 2015, EFPIA has had a staggering number of meetings – over 50 in total – and contacts with key Commission departments and officials; this is what one might expect from a level of almost institutionalised access. Added to the online disclosure of meetings with stakeholders held by Commissioners', their cabinets, and Director Generals (ie the highest levels of policy-makers), and this level of access hints at industry-capture of the policy-makers and regulators that should ensure the pharmaceutical industry is working for the public good, rather than just its own profit, power and control.

TABLE 2: EFPIA LOBBY MEETINGS WITH THE EUROPEAN COMMISSION

European Commission Directorate	Number of meetings (1 Nov 2014 to mid-March 2015)	Topics discussed
DG SANTE	14 meetings; 2 phone calls[106]	"Exchange of view and update on latest developments" in international relations, global health including access to medicines, regulatory dialogues with India & China. EFPIA presenting positions on dossiers eg Falsified Medicines Directive, or EFPIA studies eg use of conditional marketing authorisation (CMA).[107] DG SANTE's Healthcare Systems unit met with EFPIA on 11 March 2015 concerning "Follow up of the meeting with Commissioner Andriukaitis", the Commissioner for Health and Food Safety.[108] Yet, in the list of such meetings disclosed online (now a compulsory undertaking for Commissioners), there is no meeting with EFPIA listed.[109]
DG GROW	4 meetings	Includes 3 meetings with GROW Directorate on Resources Based, Manufacturing and Consumer Goods Industries, and a governing board meeting of the Innovative Medicines Initiative (see Section 3.1).[110]
DG TRADE	4 meetings	Includes 2 meetings with Trade Commissioner Cecilia Malmström's cabinet in February 2015, concerning trade negotiations and TTIP.[111] [112] Under the previous, Barroso Commission DG TRADE held 8 behind-closed-doors meetings about TTIP with EFPIA between January 2012 and February 2014 (see Section 4).
DG RTD	31 meetings[113]	Topics include "data privacy" and "antimicrobial resistance". 27 of these meetings concerned the Innovative Medicines Initiative 2 Joint Undertaking (see Section 3). EFPIA's President (the CEO of Novartis) also met with Commissioner Carlos Moedas in Davos in January 2015,[114] and Moedas' cabinet met with EFPIA in December 2014 and February 2015.[115]

BOX 6

Lobby tactics: Pre-empting clinical trials transparency with voluntary principles

EFPIA has been a very active lobby around clinical trials' data transparency (see Box 5) over the last few years. One of the lobby strategies it pursued – a classic tactic for business lobbies keen to circumvent unfavourable legislation – has been to promote a self-regulatory vision. In other words, to create a set of (non-binding) principles that claim to address the issue at stake and demonstrate that the industry is serious, when in fact, other than minor concessions it allows the industry to continue to protect its commercial interests above all else. The strategy behind this tactic is to pre-empt regulation by – seemingly – rendering it redundant.

Enter the "EFPIA-PhRMA Principles for Responsible Clinical Trials Data Sharing" – a joint venture with the US pharma trade association and major lobby group PhRMA – which were launched in January 2014.[116] These principles include that clinical trial data and reports approved in the US or EU "will be shared with qualified scientific and medical researchers upon request and subject to terms necessary to protect patient privacy and confidential commercial information." In other words, no access to the public, and no access to discretionary and unspecified "confidential commercial information" even for researchers. The principles also pledge to make public "synopses of clinical study reports" that have been submitted to EMA or the US equivalent Food and Drug Administration (FDA) once a new medicine has been approved – but of course, "synopses" do not enable full scrutiny or independent analyses of the trial data. EFPIA and PhRMA's voluntary principles, wrapped up in vague language and nice platitudes, concede very little, but may have influenced the public and policy-makers into thinking that the industry is on the right side.[117]

A classic tactic for business lobbies keen to circumvent unfavourable legislation has been to promote a self-regulatory vision

3.3. Innovative Medicines Initiative (IMI): The public-private-partnership made in heaven for EFPIA

The Innovative Medicines Initiative (IMI) is "Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients". It is a joint undertaking between the EU and EFPIA, which "supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe".[118] Behind these nice words however is a reality of the European Commission hand in glove with the pharmaceutical industry. EU taxpayer money is being given to a multi-billion industry for research and development of drugs, effectively subsidising their research costs and enabling them to capture the profits through an IP regime they authored. The priorities, direction, and decision-making structure of IMI are all grave cause for concern, with EFPIA in the driving seat, able to set goals and decide on the grants to be attributed.

Funding: IMI is now in its second phase, with a €3.3 billion budget for 2014-2024. €1.6 billion comes from the EU's current framework programme for research and innovation Horizon 2020, and €1.4 billion has been committed by EFPIA companies. The EFPIA companies' contribution is 'in kind', for example "by donating their researchers' time or providing access to research facilities or resources" – ie labs and researchers.[119] IMI's first phase, launched in 2008, was a similar set up, with a budget of €2 billion, half of from the EU's Seventh Framework Programme for research (FP7), and half from in kind contributions by EFPIA companies. One of the consequences of EFPIA's co-design and co-funding of IMI has been to provide it with unrivalled access to the European Commission: for example, EFPIA had 27 meetings concerning IMI 2 with DG RTD between November 2014 and mid-March 2015 (see section 3.3). The lack of critical evaluation of IMI by the European Commission has in turn contributed to IMI (ie EFPIA)'s success at permeating institutions like EMA, which should remain independent of the industry it regulates.

"EU pays while industry cashes in": In April 2015, the results of a six month investigation into IMI by German newspaper *Spiegel Online*, Swiss public broadcaster SRF, and the Belgian newspaper *De Standaard* was published. The investigation, which involved more than 70 interviews with researchers, politicians, pharmaceuticals and NGOs, concluded that more than €2.5 billion of taxpayer money "has been used almost exclusively to subsidize the pharmaceutical industry through the circuitous route of research."[120] Amongst the problem areas of IMI – the "conflicts of interest inherent" – is a growing gap between the development of essential medicines – one of IMIs main goals – and the projects' increasing focus on research areas that benefit

EU taxpayer money is being given to a multi-billion industry for research and development of drugs, effectively subsidising their research costs and enabling them to capture the profits through an IP regime they authored

the pharmaceutical industry. This in part stems from the way the Commission delegated the development of IMI to EFPIA during the design of the project: "the Commission's intention had been to give industry an inch, but instead it took a mile".[121]

With billions of euros of Commission-allocated public funds going to co-produce research into medicines, apparently to fit the agenda of the pharmaceutical industry, a vital question is how much big pharma would, in the absence of IMI, have spent on research projects anyway. A now removed extract from EFPIA's webpage on IMI stated that, in some cases, IMI offers pharmaceutical companies "tremendous cost savings, as IMI projects replicate work that individual companies would have had to do anyway".[122] Considering that the pharmaceutical companies involved would in any case have "spent" these "in-kind" resources on equivalent research, IMI looks more and more like a clever way for pharma to get public sector buy-in and obtain financing for their own goals.

Other major problems uncovered by the investigative journalists include a lack of transparency[123] and inadequate monitoring (individual companies' "in kind" contributions are confidential and cannot be audited).[124] The divergence of IMI research from the World Health Organization (WHO)'s essential medicines research priorities is also of particular concern, since a major part of IMI's mission is supposed to be a focus on areas of **unmet medical or social need**.[125] Yet clinical research areas such as malaria, heart disease and arthrosis were identified in *Spiegel*'s investigation as being absent in IMI, despite being WHO focus areas. This divergence from the WHO's list of unmet or essential medicinal needs is perhaps not surprising given that the profit-motivated pharmaceutical industry is structurally enabled to set the research agenda within IMI.[126]

A particularly worrying IMI project is the European Patients' Academy on Theraputic Innovation (EUPATI), which aims to increase patients' "capacity to be effective advocates and advisors, eg, in clinical trials, with regulatory authorities and in ethics committees".[127] Led by a group called the

European Patients Forum, which receives nearly 40% of its funding from pharma companies,[128]EUPATI effectively serves as a lobbying school for patients to learn to exert greater pressure at agency and health authority level. But if EUPATI is a patient lobby school, the teachers are pharmaceutical companies. There are 18 pharma companies participating in EUPATI, more than in any other IMI project, leading to concerns of it acting as a Trojan horse for big pharma. TACD sees EUPATI as an attempt to train patient advocacy groups to lobby for faster approval of medications, which in effect means the EU is investing millions in a project "that is further strengthening the already strong pharmaceutical industry lobby."[129] Other critics of the project include members – and those who've resigned in protest from – EUPATI's board. According to one board member from the University of Hamburg, who specializes in evidence-based patient information, courses for patient representatives should provide an opportunity to encourage critical thinking, including about the pharmaceuticals industry, "But I doubt that works when those leading the courses come from the firms themselves".[130]

Intellectual property rights falling into arms of industry? In 2010 IMI came under a barrage of criticism from academic circles, not only due to the tough investment requirements for universities (requiring them to put up a greater proportion of costs than other EU FP7 research programs), but also on the grounds that the design of IMI's intellectual property (IP) regime is skewed in favour of industry.[131] The League of European Research Universities (LERU) wrote to the IMI board arguing that "IMI shows how a private-public partnership should not be set up. The combination of disadvantageous financial and intellectual property rules represents a double negative when it comes to academic or SME participation."[132] LERU further condemned the way the that under "the window-dressing of IMI as a 'private-public partnership' (PPP), a new IP policy was introduced without consultation of academic institutions that saw a clear push towards providing advantages to the EFPIA partners." The EFPIA lawyers, LERU reported, rigidly assumed that both academic institutions and SMEs would "simply accept such unfavourable terms without even the pretence of negotiation", demonstrating the lack of equal partnership between industry and academic/research institutions.[133] According to a senior figure at University College London, an example of how the IP regime favours the financial interests of IMI's industry partners is that their affiliates can exploit technologies developed as part of an IMI project, without having to consult the research consortium.[134] SMEs have also complained that IMI's IP rules are biased towards large pharmaceutical companies.[135]

The IMI rules on IP have been adjusted somewhat since these criticisms in 2010. For example, there now exists an embargo that pharma companies must honour before sharing joint research findings with third parties. But the specifics of those rules are to be hashed out between the research partners eg a university and a multi-billion euro pharmaceutical transnational. According to commentators from the University of Freiburg's office for EU relations, given how large and well-resourced the legal departments of pharmaceutical companies are, it is clear how these negotiations are likely to end – which is enough to put many university researchers off.[136] EFPIA, by contrast, describes IMI's IP regime as "a favourable intellectual property policy", conducive to "producing tangible outcomes".[137] Rules on academic co-funding have also been adjusted slightly in IMI 2, but academic researchers report that they still have "to resort to tricks in order to obtain sufficient funding".[138]

What next for IMI? Despite the evident industry-capture of IMI, the Commission shows no signs of concern. Before the Juncker Commission entered office in November 2014, EFPIA wrote a briefing for the new Commission, heralding the need to "to reinvigorate R&D... through the development of a new business model built on partnership". EFPIA cited IMI as a programme that has "shown the huge benefit that well thought-through public-private partnerships can have," and one which "is of vital importance to us".[139] Perhaps more worryingly, EFPIA informed DG Enterprise that it proposes to launch a 'European strategic council for the life-sciences sector' aimed at bringing EU political authorities and industry together, which "should be co-presided by the Council of Ministers and the European Commission." Apparently so delighted with its co-option of public funds and research agendas in IMI, EFPIA is keen to further entrench its inside role and influence within the EU.

4. Commission TTIPs its hat to big pharma

4.1. Pharma's stake in TTIP, and why it matters

Big pharma has put major lobby efforts into the ongoing negotiations of the EU-US trade agreement known as the Transatlantic Trade and Investment Partnership (TTIP). Indeed, the pharmaceutical sector's TTIP lobbying dramatically increased once the preparatory phase ended and the trade talks began.[140] Negotiated behind closed doors, the aim of TTIP is to address non-tariff regulatory measures such as setting standards and legal frameworks for technical regulations, intellectual property rights, and investment protection measures. Broad segments of civil society are deeply concerned that TTIP will lower standards for consumer protection, undermine health and environmental policies, and transfer even more political power to corporations. Regulatory harmonisation is feared to mean a race to the bottom, reducing regulatory obligations to the lowest standards found on either side of the Atlantic. The secrecy and lack of transparency around the negotiations, together with the far greater access of corporate influence compared to the public, adds to the concerns that TTIP will promote the commercial interests of multinationals rather than the general interest of citizens.

The pharmaceutical industry, as one of the most powerful corporate lobbies on both sides of the Atlantic – dwarfing the capacity of public health advocates, in Europe by around 15 times (see Box 2) – views TTIP as an opportunity to push its agenda. More worryingly, the European Commission seems all too happy to let it, having uncritically promised to take the industry's wish-list "to the negotiation table".[141] Extensive contacts between the Commission and the pharmaceutical industry on TTIP, combined with pharma's demands having clearly detrimental implications for access to medicines and public health in the EU and beyond, paint a worrying picture. These demands include extended periods of monopoly through intellectual property measures, undermining regulations set by EU member states to protect public health, and directly attacking the recent EU move towards transparency on clinical trials.[142]

TTIP, IPR and innovation: Big pharma is using TTIP as an opportunity to entrench longer monopoly periods, higher medicine prices, and more "new" medicines with limited therapeutic value. IPR-type protection is a key means by which they intend to do this. Pharma argues that strong IPR protection is needed for innovation,and that there should therefore be greater IPR protection under TTIP. But as explored in Section 1 and Box 1, the problems with this view, and the IPR system more generally, are manifold. These include the fact that IPR are irrelevant for stimulating innovation in the absence of a profitable market, as in the case with diseases affecting millions of poor people in developing countries. Furthermore, the meaning of "innovation" that big pharma relies on is a blanket definition of anything "new" – regardless of whether an innovation represents therapeutic progress (ie a tangible therapeutic advance for patients).[143] Instead, many new medicines are neither safer nor more effective than those already available,[144] so the industry's profits therefore rely on high hurdles of protection that are not oriented towards usefulness, but to prevent as much competition as possible.[145]

Extensive contacts between the Commission and the pharmaceutical industry on TTIP, combined with pharma's demands having clearly detrimental implications for access to medicines and public health in the EU and beyond, paint a worrying picture.

With this in mind, the pharmaceutical industry's demands that TTIP should further entrench and strengthen IPR protections are extremely troubling. This would effectively make any action by EU member states to the contrary open to legal action by the industry through investor-state dispute settlement (ISDS), private courts for corporations to sue governments for loss of expected profits. The consequences for the provision of sustainable and affordable access to medicines are likely to be dire, both within Europe and also within low and middle-income countries. This latter is

due to the precedent-setting nature of TTIP: if big pharma succeeds at getting the deal to include "enhanced recognition" of the World Trade Organisation's controversial Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS), there would likely be dire knock-on effects for third countries, particularly in the global south.[146]

Bilateral trade agreements like TTIP provide the pharma lobby an opportunity to bolster IPR protections and lengthen the period of market exclusivity for its products. It is therefore vital that TTIP does not include IPR provisions within the definition of investment – and thereby open them up to ISDS, or within any other area of the agreement. This would enable US pharmaceutical companies to sue EU member states over measures to promote access to medicines (such as price controls, reimbursement decisions, marketing approvals and drug safety decisions, or stricter patentability standards), arguing that they would damage their investments protected by IPR.[147] Such provisions will intensify health inequalities, compromise access to affordable medicines, and hand more power and privilege to an increasingly unaccountable industry.

TTIPing point for transparency on clinical trial data: Shrouding the data obtained from clinical trials data in secrecy is dangerous for public health, because it can enable the benefits of medicines to be overrated and the harms downplayed. Citizens, medical practitioners, and researchers have the right to have access to full information on the medicines they take or prescribe. Clinical trial data cannot be considered commercially confidential information because human health is an overriding public interest (see Box 5).[148]

In the context of TTIP, the pharma lobby promotes what it describes as an "aligned approach" between the EU and US on disclosure of clinical trial data, one that takes the "impact on commercial opportunities in third countries" into consideration. Thus, this aligned approach would ensure their model of control and profit is maintained not only in the EU and US, but helps to strengthen it abroad. The pharma wish list also seeks a "harmonized list of clinical trial result data fields" with agreement on what may be disclosed to the public, after ensuring "uniform protection of confidential commercial information and trade secrets".[149] The pattern is the same – enshrining provisions for secrecy both sides of the Atlantic and ensuring control over what clinical data can be released. Pharma's efforts to use TTIP to undermine clinical trial data disclosure are highly dangerous, particularly as ISDS could enable companies to sue governments if they decide to grant public access to the clinical trial data of industry.

(Un-)Affordable medicines, at home and abroad: The pharmaceutical sector is also targeting EU member states' ability to take decisions on pricing and reimbursement (P&R) – which is essential to keeping medicines affordable – including by entrenching so-called "procedural safeguards" (such as penalties applicable to member states per day of delay on P&R decisions), many of which are designed to ensure companies have a voice in the internal pricing policies of governments. Pharma is also pursuing the inclusion of legal remedies like ISDS on P&R decisions, so that pharma companies would be able to sue governments over pricing decisions. For example, cutting a medicine price in order to respond to a public health challenge, and thereby frustrating companies' expectations of being able to impose monopoly prices.[150]

The corporate capture of policy-making, together with the threat of weakening democratic control over public health policy, are perhaps most vividly illustrated by the pharmaceutical industry's efforts to shape TTIP to its advantage – and everyone else's loss.

Because one of the objectives of TTIP is to set global standards, if big pharma gets its way, the EU-US trade agreement will have serious implications on access to medicines in third countries. The impacts could be felt particularly in the global south, where less transparency on the benefit and harm of medicines, longer monopolies, less generic competition, and limits on pricing policies will be even more harmful. Poorer countries with greater resource constraints, fewer and weaker institutions (eg health insurance and strong competition law) to balance intellectual property protection and higher prices, will have little defence against the increased power and protection of large pharmaceutical corporations, and the greater burden on public health systems and citizens will exclude more and more people from access to medicines.[151]

The lessons from history about the impacts of neo-liberal trade agreements written by rich countries, and of draconian IPR protections over urgently needed medicines, as for example with antiretroviral drugs to treat HIV/AIDS, are lessons that big pharma would rather we did not learn. Unfortunately, not learning them will have a high cost, paid by thousands of lives in countries that do not have the economic or political clout to protect their citizens from the profit-over-life model that the pharma industry is now pushing through TTIP. A model that in future is likely to be imposed on other countries by way of the asymmetric power plays that underlie negotiations of free-trade agreements between major powers, like the US or the EU, and countries less able to protect their peoples' public health needs.

The lobbying efforts of big pharma, and the cosy relationship it enjoys with the European Commission – both in the Barroso II Commission and in the Juncker Commission – are explored below. The corporate capture of policy-making, together with the threat of weakening democratic control over public health policy, are perhaps most vividly illustrated by the pharmaceutical industry's efforts to shape TTIP to its advantage – and everyone else's loss.

4.2. A front row seat for pharma in TTIP negotiations under Barroso Commission

Between January 2012 and February 2014 – a period of industry agenda-setting and full-scale offensives to shape the TTIP negotiations – DG Trade's lobby contacts about TTIP (ie participation in public consultations on TTIP, participation in Civil Society Dialogue sessions, and behind closed door meetings) show significant activity from the pharmaceutical sector. EFPIA had eight behind closed door meetings with DG Trade, Eli Lilly had four, Johnson & Johnson and EGA each had three, whilst Roche, Pfizer and MSD Sharp & Dohme all had two. GlaxoSmithKline, AESGP, EUCOPE, US Generics Pharma Association (GphA) and PhRMA also met at least once with DG Trade in this period.

Documents released to CEO under access to documents laws shed further light on the nature of some of the Commission's correspondence and meetings with big pharma during this period.

TABLE 3: BIG PHARMA LOBBY AND THE BARROSO COMMISSION

Company	Meeting details	Key issues/ notes from CEO
Pfizer	EU trade delegation meeting in USA, Nov 2013	– Pfizer expressed its "strong support for TTIP, as the company realizes the opportunity to tackle[,] in particular[,] regulatory barriers"[152]
Business Coalition for Transatlantic Trade (BCTT)	Met DG Trade and DG MARKT, Oct 2013 (meeting included representative from BCTT member Johnson & Johnson)	– BCTT presented its TTIP IPR chapter priorities, including "cooperation vis-a-vis 3rd markets, data exclusivity for pharmaceuticals... and protection of trade secrets";[153] the Commission noted the position and "welcomed further submissions".
Eli Lilly	Met Trade Commissioner De Gucht's cabinet, March 2013 (including CEO, Brussels Lilly employee, & their lobbyist from Fleishman-Hillard[154])	– Lilly's CEO John Lechleiter expressed strong support for TTIP "which should be comprehensive and ambitious, addressing regulatory harmonisation, intellectual property market provisions...and public procurement measures" plus "set ambitious goals on regulatory harmonisation aspects, including mutual recognition and clinical trials".[155]
	Met De Gucht's cabinet, DG TRADE, November 2013	– Commission notes show Lilly more or less threatened that if it didn't get its way, the industry would simply leave: in a "statement on risk for future investments", Eli Lilly warned that "if pricing and reimbursement and IPR protection are not favourable to an industrial base in the EU... Nothing impeaches that future investments go elsewhere."[156]
German Pharmaceutical Industry Association (BPI) & EUCOPE	Met DG Trade, December 2013	– DG Trade privileged BPI and EUCOPE with a "general overview of the timing and the content" of the TTIP negotiations.[157] – BPI said TTIP is "an opportunity to address industry's concerns on finding ways to disclose data while ensuring a certain level of protection for commercial confidentiality". – BPI said commercial confidentiality is the "only way to protect products for companies that do not have patents protected in foreign countries", and a common approach on what is considered confidential information should be agreed "on the basis of a case-by-case analysis."
EFPIA	DG Trade – numerous and frequent meetings (11 meetings between Jan 2012 and Feb 14)	– TTIP meetings described by Commission as "friendly atmosphere" and "very productive"; Commission routinely updated EFPIA on status of negotiations.[158] – In a more recent meeting between an EFPIA representative and the EU delegation in the US about a potential innovation chapter in TTIP, in June 2014, EFPIA lobbied for the inclusion of "upstream regulatory cooperation that would start way before a regulatory initiative has been put on the table".[159] – In other words, the industry wants a formal seat at the table at an even earlier stage of the policy-making process, because shaping the agenda of a yet-to-be-proposed regulatory initiative would give it maximum influence. This bold demand for institutionalised industry access and input at these crucial early stages was welcomed by the Commission, who warmly encouraged "more specific suggestions on his side".
	Meeting with DG Trade & DG SANCO (the predecessor to DG SANTE, with a remit on health and consumers), February 2014	– 3 EFPIA representatives, joined by member companies Eli Lilly and Roche, lobbied the Commission to ensure the US and EU have the same, single, clinical data requirements.[160]

Company	Meeting details	Key issues/ notes from CEO
EFPIA & PhRMA – represented by **Eli Lilly** and **Biogen Idec** respectively	EU-U.S. High Level Regulatory Cooperation Forum (HLRCF) in April 2013	– The pharma trade associations described the biopharmaceutical industry as "Valuable but Vulnerable".[161] – They also claimed that "80% of the total potential gains [from TTIP] will come from cutting costs imposed by unnecessary bureaucracy and regulations, as well as from liberalizing trade in services and public procurement". – EFPIA and PhRMA stated that "Harmonization of regulations facilitates investment in R&D of new, innovative medicines targeting unmet patient needs around the globe" and that therefore it "is vital that all stakeholders – regulators, industry, policymakers and healthcare providers – collaborate". One cannot fail to note the absence of public health groups or other civil society from their list of "all stakeholders". – They also demanded "a harmonized list of clinical trial result data fields" and agreement "on which of these data fields may be disclosed to the public" - the latter of course implies that some of it should not be. – Another demand was for "EU / US uniform protection of confidential commercial information and trade secrets, consistent with shared obligations under Article 39.3 of the WTO TRIPS Agreement".
40+ industry participants included 3 from **EFPIA**, & representatives from **GlaxoSmithKline** & **Teva**	European Commission industry stakeholder meeting on the IPR Chapter in TTIP, attended by DG TRADE, DG MARKT, DG TAXUD, and DG AGRI, April 2012	– The most strongly supported priorities included "the need for both sides to enforce protection of trade secrets" and "the importance of EU and US cooperating to promote high levels of IP protection and enforcement in 3rd countries". – On patents, EFPIA specifically intervened to express concerns about "IP erosion, cost of litigation and enforcement, the need for the US and EU to keep ahead on innovation processes."[162] (See Section 3 for more on EFPIA.)

4.3. The Juncker Commission: Keeping pharma close on TTIP

The start of the Junker Commission in November 2014 has certainly not marked a break in the close cooperation between the European Commission and the pharmaceutical industry regarding its interests in TTIP. The lead negotiators for the pharmaceuticals and medical devices negotiating areas in TTIP are from DG Health and Food Safety (SANTE).[163] As well as industry lobby meetings with DG SANTE on TTIP, the online publishing of Trade Commissioner Cecilia Malmström and her cabinet's correspondence with stakeholders reveals considerable attentions from big pharma.[164] The Trade Commissioner's office have received numerous invitations and correspondence, as well as being involved in several meetings with big pharma.

TABLE 4: BIG PHARMA LOBBY AND THE JUNCKER COMMISSION

Company / lobbyist / association	Meeting, invitation or correspondence details	Key issues/ notes from CEO
EFPIA	Two meetings with Trade Commissioner Cecilia Malmström's cabinet in February 2015	– One meeting on the subject of "TTIP" and one on "Trade negotiations and health."[165]
EFPIA	Meeting with DG SANTE 'medicinal products, authorisations and EMA' unit, 12 December 2014	– The meeting was an "Exchange of view and update on latest developments in international relations, in particular ongoing legislative initiatives in the Unites States of America, Transatlantic Trade and Investment Partnership (TTIP) and other topics".[166]
EFPIA, AESGP, & EGA	Meeting with DG SANTE 'medicinal products, authorisations and EMA' unit, plus a SANTE official from 'medicinal products: quality, safety and efficacy' unit, 16 February 2015	– As above.
Medtronic	Meeting with Trade Commissioner Cecilia Malmström's cabinet, 4 March 2015	– The world's third largest medical device company discussed "Medical device and TTIP" with the Trade Commissioner's cabinet.[167]

Company / lobbyist / association	Meeting, invitation or correspondence details	Key issues/ notes from CEO
European Centre for International Political Economy (ECIPE), Alliance for Healthcare Competitiveness (AHC)	Invitation to Trade Commissioner Malmström (declined)[168] – to a roundtable discussion on "the role of healthcare in advancing innovation, economic development and global health through key trade negotiations, particularly with regards to the Transatlantic Trade and Investment Partnership (TTIP)" in Brussels, March 2015.[169]	– Invite from neoliberal trade policy think tank ECIPE and AHC, a healthcare employers association whose members include Abbott, Johnson & Johnson, Medtronic and PhRMA)[170] – The roundtable (which the Commissioner could not attend) was to focus on "opportunities to enhance health innovation and patient access to care by reducing trade barriers and increasing harmonization between the European Union and the United States". – ECIPE and AHC's high-level lobby attempts raise concerns about transparency. ECIPE, despite declaring seven full time lobbyists in the Transparency Register, declaresspending less than €9,999 on EU lobbying in 2014[171] - a dubiously low declaration. AHC is absent from the register (as of April 2015), despite clearly being involved in EU pharmaceutical lobbying, being listed as a client by Edelman Public Relations Worldwide,[172] and explicitly seeking the "Inclusion of health services in the TTIP agreement"[173]
Novartis	Novartis CEO sought meeting with Trade Commissioner Malmström at World Economic Forum in Davos, January 2015 (unsuccessful)	– Meeting's proposed agenda (which the Commissioner could not attend) was "to discuss how Novartis can contribute to strengthening the EU's global leadership through trade policy".[174] – The Chief Executive of Swiss pharmaceutical giant Novartis Joseph Jimenez pointed out in his correspondence that he is also now President of EFPIA and Chair of PhRMA – both the EU and US' major pharma trade lobbies. Insisting that "solid IP provisions in trade agreements" are the only way for the pharmaceutical industry to retain its global leadership, the Novartis boss was keen to discuss "how the pharmaceutical industry as a whole can get involved". – In the Transparency Register Novartis declares spending between €1.5 - €2 million on EU lobbying in 2014, as well as having five lobbyists with Parliamentary access passes[175] and employing lobby consultancy Acumen Public Affairs.[176]
VCI (German chemical industry trade association)	VCI President invited Commissioner Malmström to be guest of honour at a European Parliamentary Reception in Brussels, May 2015 (unknown if accepted)[177]	– The Parliamentary Reception was intended to discuss "how to tackle the challenges that the chemical-pharmaceutical industry is currently facing".[178] – VCI made clear in its correspondence that the chemical-pharmaceutical industry "is an ardent supporter of further trade liberalisation and strongly supports the Juncker-Commission's priority of establishing an ambitious and comprehensive agreement with the United States". – VCI views "regulatory cooperation section in the TTIP as a new milestone for developing the next generation of international trade rules". – In the Transparency Register VCI declares spending between €3.5-€4 million euros on EU lobbying in 2014 and has 26 full-time equivalent lobbyists.

BOX 7

E-cigarettes: Pharma lobbying on controversial EU tobacco products law

Background: The negotiation of the EU Tobacco Products Directive, which entered into force in May 2014 after formal approval from the European Parliament in February 2014 and European Council March 2014, was one of the most fraught lobbying battles of recent years. Not only because it concerned the multi-billion tobacco industry, which profits from harm and has a long history of misinformation and manipulation, but because of the entry onto the scene of a new product, the e-cigarette.

E-cigarettes contain nicotine but not tobacco, and therefore cross onto the turf of one of the pharmaceutical industry's big sellers – nicotine replacement therapies (NRTs) aimed at helping smokers quit, such as nicotine patches or gum. The smoking cessation market is dominated by brands such as Novartis' Nicotinell, GlaxoSmithKline's NiQuitin and Pfizer's Nicorette – products whose sales have dropped since the rise of e-cigarettes.[179]

It appeared that the pharmaceutical industry was therefore keen to ensure that e-cigarettes be classed as medicine; the costly process of getting a product thus registered would push many of the smaller e-cigarette manufacturers out of the market. Leaving pharmaceutical companies, which have the resources to undertake the cost of clinical trials etc, to muscle in on the e-cigarette market.[180]

Under the Commission's original TPD proposals, e-cigarettes would have been classified as a medicine, subjected to clinical testing and possibly only been available in pharmacies in some countries. The process of getting a product licensed as a medicine is costly. As a result, lobbying on the issue of e-cigarette classification and restrictions in the TPD was voracious, with arguments put forth that this would kill the "cottage-industry" of e-cigarette manufacturers, and force people to keep smoking. When CEO reported on some of the e-cigarette lobby tactics, including MEPs receiving free e-cigarettes in their letter boxes, and hundreds of emails apparently from e-cigarette users making emotive pleas not to "ban" e-cigarettes, the reaction from the e-cigarette industry and users was equally voracious, claiming that the 'real lobbyists' on e-cigarettes was big pharma.[181]

Pharma urges DG SANCO to classify e-cigarettes as medicines: According to results from access to documents requests, pharmaceutical industry players were indeed actively lobbying on the TPD and the regulation of e-cigarettes.[182]

For example, the Association of the European Self-Medication Industry (AESGP), including representatives of companies producing NRTs GlaxoSmithKline (GSK) and Johnson & Johnson met with DG SANCO in May 2013, arguing that "all nicotine containing products (with the exception of tobacco)" should be classed as medicine.[183] GSK also had extensive email correspondence with DG SANCO on the same topic, the release of which caused something of a media stir in February 2014.[184] The general analysis was that pharma companies' primary concern was the threat posed by e-cigarettes to nicotine gum, patches and tablets.

There is clear evidence that the pharmaceutical industry, among others, was promoting its interests during the negotiation of the TPD by lobbying for e-cigarettes to be regulated as medicines. Out of 41 released documents of correspondence between DG SANCO and lobbyists between July and December 2013, nine related to the pharmaceutical industry. The rest pertained to tobacco industry correspondence.[185]

5. Conclusion

The pharmaceutical industry holds the reigns of a vast and well-resourced lobbying machine in Brussels, enjoying almost systematic access to European Commission decision-makers. This breeds serious fears over excessive influence of big pharma on EU decision-making, to the detriment of public health and trade justice.

The colossal, multi-million lobbying expenditure from pharma companies, trade associations, and lobby firms acting on their behalf, dramatically dwarfs the spending of civil society public health and access to medicines advocates by around 15 times. Extensive meetings with policy-makers – including over 50 meetings with EU pharma trade association EFPIA in the first four and half months of the Juncker Commission – and participation in Commission advisory groups are some of the channels of influence that the pharmaceutical industry uses to promote its interests.

A major rebalancing of interests is urgently needed, beginning with full transparency over industry lobbying and influence. This can can only come through a truly mandatory EU lobby register, both monitored and sanctioned, as well as full and automatic disclosure of lobby meetings at all levels of policy-makers – not only the highest-level, which leaves transparency around lobby contacts for the bulk of Commission officials dependent on time-consuming and often incomplete access to documents requests.

An end to industry representatives sitting on advisory groups in their "personal capacity" is long overdue, as is a publicly demonstrated rebalancing of interests in expert groups. This needs to be accompanied by a shift away from the regulatory culture that fails to see the profit-motivated interests of the regulated as being at odds with the public-good motivated responsibilities of the regulator.

There has been an effective capture of the narrative around medicine and health policies by the pharmaceutical industry agenda, which makes its role and legitimacy unassailable in the minds of many. Thus the pharmaceutical industry's rhetoric can often win over both the public and policy makers with language about property rights fuelling 'innovation' and 'research', while framing regulation of the sector as a 'barrier' to the same. Meanwhile the capture of EU research funding through public-private projects like IMI grows apace. Greater understanding of the reality behind the rhetoric is urgently needed, as a first step to making one of the world's most profitable, most powerful, and most problematic industries fit to serve the goals of public health.

Shining a light on the pharmaceutical lobby's firepower, and deconstructing its agenda, is a crucial step in serving genuine public health needs, and truly facilitating access to essential medicines the world over.

One of the clearest examples of the political consequences of the firepower of the pharmaceutical lobby is the way that secrecy around clinical trials results is being pushed by big pharma's lobbying on TTIP. Citing "commercial confidentiality" it is effectively denying patients, doctors, and researchers access to unbiased information about the safety and efficacy parameters of a drug, based on both the results and the methodologies of its testing.

Shining a light on the pharmaceutical lobby's firepower, and deconstructing its agenda, is a crucial step in serving genuine public health needs, and truly facilitating access to essential medicines the world over.

Appendix

Methodology for identifying pharmaceutical companies in the Transparency Register (TR):

The 40 pharmaceutical companies identified in the TR (as of 04/04/15) were identified first by searching "pharmaceutical" in the TR search function, then narrowing this down to those listed under the category "Companies & groups" (a sub-category of Section II – In-house lobbyists and trade/business/professional associations). An individual search was also carried out for all EFPIA member companies in the TR. All pharmaceutical companies named in the 2012 CEO& HAI 'Divide and Conquer' report were also searched for individually. Major chemicals companies which also have pharmaceutical branches/subsidiaries were not included unless they are also members of EFPIA, eg Bayer.

Methodology for identifying pharmaceutical trade associations in the Transparency Register

The 18 pharmaceutical trade associations identified in the TR (as of 11/04/15) were identified first by searching "pharmaceutical" in the TR search function, then narrowing this down to those listed under the category "Trade and business associations" (a sub-category of Section II – In-house lobbyists and trade/business/professional associations). An individual search was also carried out for all pharmaceutical trade associations named in the 2012 CEO& HAI 'Divide and Conquer' report. Trade associations of pharmacists (eg the Royal Pharmaceutical Society of Great Britain (RPS)) were not included in the results.

Methodology for identifying pharmaceutical trade associations in the Transparency Register

The 25 lobby consultancies with one or more pharmaceutical industry client identified in the TR (as of 13/04/15) were identified via several search steps. Firstly, the lobby consultancies with pharmaceutical industry clients named in the 2012 CEO & HAI 'Divide and Conquer' report were searched for individually to ascertain whether they still had one or more pharma client. Secondly, all pharmaceutical companies and trade associations identified in the TR under the previously described two search methodologies were searched for by name, with the result that any lobby consultancy they are listed as a client of would show up in the search results. Thirdly, EFPIA members not signed up to the TR were searched for by name, with the result that those named as a client by any lobby consultancy in the register would show up in the search results.

Methodology for identifying civil society groups working on medicines/public health issues in the Transparency Register

The eight non-governmental/non-profit/civil society organisations working on medicines/pharmaceutical/public health issues and related dossiers at EU level were identified first by searching the TR (as of 01/07/15) for those organisations named in the 2012 CEO & HAI 'Divide and Conquer' report. A further search was done of organisations which appeared under the search for "pharmaceutical" in the TR and were listed under the Section III – Non-governmental organisations. These were then considered, discounting organisations which receive funding from, or partner with, the pharmaceutical industry, and including organisations which focus on public health, consumer organisations and groups working on access to medicines.

Disclaimer: The lists resulting from the search methodologies detailed above cannot be guaranteed to be exhaustive, and resulting data may be subject to omissions resulting from the TR's own search engine, as well as reasonable human error or omission. The data in the TR is changing constantly, with some entries updated on any given day. The data in this report therefore only represents the TR data for the specific dates that the research was carried out, as stated in the methodology, or where other dates are provided in the text or footnotes of this report ["as of DD/MM/YY"]. Any subsequent changes or additions to the Transparency Register are therefore not accounted for, and this report makes no claims to the accuracy of the data for any other dates than those given in the report.

Notes

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3. TACD IP Policy Committee blog, Pharma is moving fast, *ibid.*
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5. TACD, IP Policy Committee blog, European Commission and Council´s new "Pharmish" terms on access to medicines, by David Hammerstein, 18 February 2015, http://tacd-ip.org/archives/1305
6. TACD, IP Policy Committee blog, European Commission and Council´s new "Pharmish" [...], *ibid.*
7. Unblinding the public, *ibid.*
8. Unblinding the public, *ibid.*
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10. Unblinding the public, *ibid.*
11. World Health Organization, Public Health, Innovation and Intellectual Property Rights: Report of the Commission on IP Rights, Innovation and Public Health, 2006, http://bit.ly/1uaTfow
12. European Competition Pharmaceutical Sector Inquiry, Final Report (2009), http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry
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14. TTIP: A Civil Society Response to the big pharma wish list, *ibid.*
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16. Ben Goldacre, *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients Bad Pharma*, 2012, p. ix and xi
17. Ben Goldacre, *ibid.* p.xi
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25. *ibid.*
26. *ibid.*
27. See appendix for how this representative but not necessarily exhaustive list of eight civil society organisations was identified. The calculation is based on their maximum estimated lobby expenditure declared in the TR as of 01/07/15, and the eight organisations are European Public Health Alliance (EPHA), Health Action International (HAI Europe), European Consumers Organisation (BEUC), Which?, the AGE Platform, Association Mieux Prescrire, Africa Europe Faith and Justice Network (AEFJN), Access to Medicine Foundation.
28. TR: EFPIA, 2014 lobby expenditure of € 5,071,000; and Bayer, 2014 lobby expenditure of € 2,460,000.
29. Number of lobbyists (both no. FTE and no. accredited to the European Parliament) of lobby consultancies

employed by pharma industry actors have not been included in this estimate, as it is not possible to estimate how many of their total lobbyists are working on behalf of pharma clients and for what proportion of their time.

30. CEO and HAI, Divide & Conquer, *ibid.*

31. This may in part be due to the update of the Transparency Register's guidelines and declaration requirements, as well as the introduction by EFPIA of guidelines for its members (which many of the pharmaceutical companies in the register are a member of).

32. TR: Alexion Pharmaceuticals, last modified on: 06/02/2015, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=611074012464-89, and G Plus Ltd, last modified on: 28/04/2015, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=7223777790-86

33. TR: Stallergenes, last modified on: 04/03/15, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=200207410672-48, and FTI Consulting Belgium, last modified on: 20/04/2015, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=29896393398-67

34. Based on the TR entries of these firms, as of 13/05/15

35. Community Public Affairs, Edelman Public Relations Worldwide, Grayling, APCO Worldwide, Rohde Public Policy. Based on their respective TR entries, as of 13/05/15

36. Interel European Affairs, FIPRA International Limited, Fleishman-Hillard, Rohde Public Policy, Marking Public Affairs bvba. Based on their respective TR entries, as of 13/05/15

37. Based on TR entries of Interel (Astellas listed as client for below €9,999 in 2014) and Hill & Knowlton (Chiesi Farmaceutici SPA listed as a client for €25,000 to €49,999 in 2013), as of 13/05/15.

38. 04/12/2014 DG ENTR/F/4 meeting with GSK (DG GROW A2D request, *ibid.)*
GSK meetings with DG RTD Health Directorate 03/11/2014; 13/11/2014 (with Janssen Diagnostics); 19/11/2014 (with Friends of Europe); 25/11/2014, 18/12/2014, 08/01/2015, 12-13/01/2015, 27/01/2015 (all with Janssen Vaccines, Merck vaccines); 12/12/2014 (with J&J); 14/01/2015; 23/01/2015 (with EFPIA, AstraZeneca, J&J, Lundbeck, UCB); 4-5/02/2015 (with Sanofi, Roche, Merck Seronon, DaiichiSankyo, Genzyme, Orionpharma, Pfizer, J&J and UCB pharma); 10/03/2015; 12-13/03/2015 (with Vaccines Europe, Novartis Vaccines, Sanofi pasteur, Fraunhoher IME, Takeda, Janseen, Sclavo Vaccines Association, Pfizer). According to RTD A2D request, *ibid.*

39. 19/11/2014 DG ENTR/F/4 meeting with NOVARTIS (DG GROW A2D request, ibid.)
Meetings of Director-General Daniel Calleja Crespo with organisations and self-employed individuals, http://ec.europa.eu/transparencyinitiative/meetings/meeting.do?host=66b9a93e-bac3-4820-8f21-9576b54e3428, as of 24/04/15. 13/03/2015 Brussels, NOVARTIS INTERNATIONAL AG re. Industrial Policy for pharmaceuticals
DG RTD Health directorate meetings with Novartis 26/11/2014 (plus EFPIA et al.), 27/01/2015, 12-13/03/2015 (with Vaccines Europe et al.) (RTD A2D request, *ibid.)*
DG SANTE meetings with Novartis 2014.11.21 Unit D5 – medicinal products, authorisations and European Medicines Agency (with EUCOPE); 10.02.2015 Unit D2 – Healthcare Systems Head of Unit; 2014.11.14 Unit C1 Programme Management and Diseases. (DG SANTE A2D request, *ibid.*)

40. DG SANTE Health systems and products unit 2015.02.04 meeting with Johnson&Johnson (with Janssens Company group) re. Exchange of views on latest development in the area of Health system' sustainability/performance assessment and adaptive pathway/HTA. (SANTE A2D request, ibid.)
DG RTD Health directorate meetings with Johnson & Johnson 26/11/2014 (with EFPIA et al.); 12/12/2014 (with GSK); 19/01/2015 (with GSK, Vibalogics, et al.); 23/01/2015 (with EFPIA et al.); 4-5/02/2015 (with GSK, Sanofi, et al.); 11/03/2015. (RTD A2D request, *ibid.)*

41. Meetings of Cabinet members of Commissioner Elżbieta Bieńkowska, *ibid.,* 21/01/2015 Brussels Belgium, SANOFI re. A reflection on how Europe can move towards the development of a genuine European Research Area, benefiting from closer cooperation between the private and the academic and public sectors and better exploit the links between fundamental and translational research.
Meetings of Cabinet members of President Jean-Claude Juncker, ibid., 19/02/2015 (Cancelled) Berlaymont, SANOFI re. Exchange of views in the perspective to present of Health & Growth and to discuss ERA, medicine development and its access for the patient; 27/03/2015 (Cancelled) Berlaymont, SANOFI re. How to strengthen a European coherent approach with focus on ERA development, ways to reduce the fragmented approach in Europe for evaluation the value of new medicines for improved access for the patient, and means of creating a more dynamic environment for medicine development in Europe and driving an ambitious agenda allowing the European life sciences sector to remain competitive on a global scale.
DG SANTE unit D1 – Strategy and international meeting with Sanofi 2014.11.20 (with EFPIA and Bayer) re.Exchange of views and update on latest developments in global health including access to medicines, the January 2015 World Health Organisation (WHO) Executive Board, and the post-2015 Sustainable Development Goals. (DG SANTE A2D request, *ibid.*)
DG RTD Health directorate meetings with Sanofi 26/11/2014 (with EFPIA et al.); 04/12/2014; 4-5/02/2015 (with GSK, Roche, et al.); 12-13/03/2015 (with Vaccines Europe et al. (RTD A2D request, *ibid.)*

42. Meetings of Cabinet members of Commissioner Elżbieta Bieńkowska, *ibid.,* 27/01/2015 Brussels Belgium, Pfizer Inc. re. Introductory meeting
Meetings of Cabinet members of Commissioner Vytenis Andriukaitis, *ibid,,* 02/03/2015 Brussels Pfizer Inc. re. Access to innovative medicine
DG TRADE 25/02/2015 Meeting with one representative of Pfizer and two representatives of Sanofi (not exclusive meeting with pharmaceutical industry) on the framework of EU-Canada Roundtable for business on CETA. (DG TRADE A2D response, ibid.)
DG RTD Health Directorate meeting with Pfizer 4-5/02/2015 (with GSK, Sanofi, et al), 12-13/03/2015 (with Vaccines Europe,et al.) (RTD A2D request, *ibid.)*

43. Meetings of Cabinet members of Commissioner Elżbieta Bieńkowska, *ibid.,* 21/01/2015 Brussels, Eli Lilly and Company re. Intro meeting
Meetings of Cabinet members of Commissioner Vytenis Andriukaitis, ibid., 03/03/2015 Brussels, Eli Lilly and Company re. Animal health and welfare, food security *[listed twice, once as cancelled, and so assumed that it went ahead on the other occasion];* 06/02/2015 Brussels, Eli Lilly and Company re Access to innovative medicine
DG RTD Health directorate meetings with Eli Lilly

26/11/2014 (with EFPIA et al.); 21/01/2015 with Stop TB Partnership. (RTD A2D request, *ibid.)*

44. 25/11/2014 Novozymes DG ENTR/F (DG GROW A2D request, *ibid.)*
Meetings of Cabinet members of First Vice-President Frans Timmermans, *ibid.,* 25/03/2015 Novozymes re. Circular Economy.
Meetings of Cabinet members of Commissioner Cecilia Malmström, *ibid.*, 19/02/2015 Brussels, Novozymes re. Green Goods negotiations.

45. 21/11/2014 CELGENE DG ENTR/F/4; (DG GROW A2D request, *ibid.*)
Meetings of Cabinet members of Commissioner Vytenis Andriukaitis, *ibid.*, 04/02/2015 Brussels, CELGENE re. Access to innovative medicine

46. DG SANTE Unit C1 Programme Management and Diseases meeting 2015.03.05 with Novo Nordisk re. Diabetes Presentation of projects in diabetes, such as our newly launched "Cities Changing Diabetes" project and a representative from the Health Promotion Centre at the Steno Diabetes Center to present some of their projects in the prevention of diabetes. (DG SANTE A2D request, *ibid*.)
DG RTD Health directorate meeting with Novo Nordisk 26/11/2014 (with EFPIA et al.). (RTD A2D request, *ibid.)*

47. TR: EKHA, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=582565214754-24, last modified: 27/04/2015

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49. TR: Interel, ibid.

50. TR: European Respiratory Society, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=38091528151-27 last modified 06/02/2015

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52. ERS, Leadership, http://www.ersnet.org/about-us/leadership.html?view=category and Elisabeth Bel, President, http://www.ersnet.org/about-us/leadership/item/bel-2.html?category_id=50

53. ERS, Guy Joos, Vice-President, http://www.ersnet.org/about-us/leadership/item/joos-2.html?category_id=50

54. TR: Weber Shandwick, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=52836621780-65, last modified on: 12/06/2015

55. TR: EUGMS, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=594468910180-73 last modified on: 08/04/2015,

56. EUGMS, Sponsorship, http://www.eugms.org/about-us/sponsorship.html

57. TR: EUGMS, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=594468910180-73 last modified on: 08/04/2015, and Marking Public Affairs bvba, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=56165887498-11, last modified on: 09/03/2015, EUGMS client bringing revenue of 10,000 € - 24,999 € in 2014

58. TR: EAACI, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=567788614987-34, last modified 11/02/2015

59. EAACI, Founder Sponsorts,http://www.eaaci.org/organisation/founder-sponsors/founder-sponsors.html

60. TR, Interel, ibid. EAACI client bringing revenue of 50,000 € - 99,999 € in 2014.

61. This estimate does not include associations of pharmacists, of which there are several in the TR.

62. In 2012, 22 pharmaceutical trade associations were identified, together spending max. 2.3 million. CEO and HAI, Divide & Conquer, *ibid.*

63. 3/11/14, GIRP, SANCO/B2 GROW/I4. According to DG GROW response to A2D requests*, ibid.*
2014.11.11 SANCO Unit D6 – Medicinal products: Quality, Safety and Efficacy, meeting with GIRP. 2014.12.16, SANTE Unit D6 meeting with GIRP (together with EFPIA, EGA, EAEPC, PGEU). According to DG SANTE response to A2D requests, *ibid.*

64. Meeting 25/03/15 AESGP, GROW/I. According to DG GROW response to A2D requests, *ibid.*
Meetings of Cabinet members of Commissioner Elżbieta Bieńkowska with organisations and self-employed individuals, http://ec.europa.eu/transparencyinitiative/meetings/meeting.do?host=85ded49b-f5bb-486e-9404-b864a34d8340, as of as of 24/04/2015. 09/01/2015 AESGP re. Introductory meeting to discuss the Self-Medication Industry
2014.12.02 SANTE Unit D6 – Medicinal products: Quality, Safety and Efficacy meeting with AESGP. SANTE A2D request, ibid.

65. Meetings with DG SANTE Unit D5 medicinal products, authorisations and European Medicines Agency 2014.11.21, Novartis, EUCOPE; 2015.01.14 EUCOPE, 2015.01.16 EUCOPE, NJORD Law Firm, plus SANTE Unit A2 Legal affairs. Meeting with Unit D6 – Medicinal products: Quality, Safety and Efficacy Deputy, 2014.11.19 EUCOPE. According to DG SANTE response to A2D requests, *ibid.*
Meetings of Cabinet members of Commissioner Vytenis Andriukaitis with organisations and self-employed individuals, http://ec.europa.eu/transparencyinitiative/meetings/meeting.do?host=e59c4da1-3434-4ddf-aa47-ade4c7dd0396&d-6679426-p=1 , as of 22/04/15.
13/04/2015 Brussels, Eucope, re. off-label use of medicines

66. DG SANTE (various units) meetings with EGA, 7.01.2015, 30.01.2015 (together with APMI Actavis Hospira Mylan Rowex, JV Sandoz Teva), 2014.12.15, 2014.12.16 (together with EFPIA, GIRP, EAEPC, PGEU) 2015.01.20, 2015.02.16 (together with EFPIA and ESGP), 2014.12.05. SANTE A2D request, *ibid.*
DG RTD Health directorate meeting with EGA 26/02/2015. RTD A2D request *ibid.*

67. Meetings of Cabinet members of Commissioner Vytenis Andriukaitis*, ibid.* 04/02/2015 Brussels EGA re. EGA manifesto; and 18/12/2014 Brussels EGA re. Pharma policy coordination; European semester process; COM 2015 workplan for pharmaceuticals.
Meetings of Cabinet members of Commissioner Cecilia Malmström, *ibid.,* 10/12/2014 Brussels, EGA, Presentation of the association
Meetings of Cabinet members of Commissioner Elżbieta Bieńkowska, *ibid,* 06/03/2015 Brussels, EGA re. Intro meeting;
Meetings of Cabinet members of Commissioner Carlos Moedas, *ibid.* 26/02/2015 Brussels EGA re. Generic

medicines and biosimilars
Meetings of Cabinet members of President Jean-Claude Juncker with organisations and self-employed individuals, http://ec.europa.eu/transparencyinitiative/meetings/meeting.do?host=91b45ce8-2ff0-4e67-b5b5-b42151217f13&d-6679426-p=2, as of 22/04/15. 24/03/2015 Berlaymont EGA re. European Union's policies affecting the pharmaceutical sector.

68. DG SANTE Unit D6 – Medicinal products: Quality, Safety and Efficacy meetings with Farmindustira 2014.11.24 and 2014.12.17. According to DG SANTE A2D request, *ibid.*

69. DG SANTE, 2015.03.04 Unit D6 – Medicinal products: Quality, Safety and Efficacy meeting with EALTH, 2015.3.16 Various units meeting with EFPIA and APRaD. According to DG SANTE A2D request, ibid.

70. European Alcohol and Health Forum (E02224) – Active, http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2224&NewSearch=1&NewSearch=1; Technical Expert Group for the implementation of the Directive on the protection of animals used for scientific purposes (E02551) – Active, http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2551&NewSearch=1&NewSearch=1; Expert group on Corporate Responsibility in the field of Pharmaceuticals (E02558) – Active, http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2558&NewSearch=1&NewSearch=1, as of 04/06/15

71. Listed as "Not a member" are NGOs Action for Global Health and Médecins sans frontières.

72. Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering (E02973) – Active, http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2973&NewSearch=1&NewSearch=1, as of 04/06/15

73. Linked-in, Gautier PEREIRA, Senior Legal Manager at GSK and Member of European Commission expert group on biotech, https://www.linkedin.com/profile/view?id=183139378authType=NAME_SEARCH&authToken=q2Gy&locale=en_US&trk=tyah&trkInfo=clickedVertical%3Amynetwork%2Cidx%3A1-1-1%2Ctarid%3A1433424518575%2Ctas%3AGautier%20Pereira, as of 04/06/15

74. Ginger IP, Professional Business Consulting, http://www.gingerip.com/home.html

75. EuropaBio, Members, www.europabio.org/members, as of 04/06/15

76. Commission expert group on rare diseases (E03015) – Active, http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3015&NewSearch=1&NewSearch=1

77. TR: GSK, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=7990322925-77, "Expert groups (European Commission): EC Expert Group on Rare-Diseases (on behalf of EuropaBio)" last modified on: 27/04/2015

78. EURORDIS, 2013 Financial report, http://www.eurordis.org/sites/default/files/financial-report-2013.pdf, and Financial information, http://www.eurordis.org/financial-information-and-funding#tabs-2

79. EURORDIS, ERTC, http://www.eurordis.org/ertc,

80. EURORDIS, About Orphan drugs, http://www.eurordis.org/about-orphan-drugs, Orphan medicines legislation, http://www.eurordis.org/content/promoting-orphan-drug-development

81. EURORDIS, ERTC membership, http://www.eurordis.org/content/join-ertc, Purpose and aims, http://www.eurordis.org/content/eurordis-round-table-companies-purpose-and-aims. AstraZeneca, Celgene, Pfizer are Ruby members of ERTC, which requires a financial pledge of 25,000 €.

82. For example, Maria Trallero, moved from DG Trade to EFPIA – see CEO, The revolving door: greasing the wheels of the TTIP lobby, 15 July 2015, http://corporateeurope.org/revolving-doors/2015/07/revolving-door-greasing-wheels-ttip-lobby#Maria_Trallero

83. For the purpose of this calculation, chemical companies with some pharmaceutical interests were not included (unless members of pharma industry association EFPIA), nor were think-tanks or groups which receive pharma funding. Pharmaceutical industry clients are therefore pharmaceutical or medical technology companies or trade associations. None the less, these figures are approximate and subject to human error.

84. Based on the TR entries of these firms, as of 13/05/15

85. Article VII, Inter-institutional agreement for Transparency Register, http://eur-lex.europa.eu/legal-content/en/TXT/?uri=uriserv:OJ.L_.2014.277.01.0011.01.ENG

86. Meetings of Cabinet members of Commissioner Elżbieta Bieńkowska, *ibid.* 22/01/2015 Brussels, Belgium, meeting with FIPRA International Limited re. Life sciences sector

87. TR: FIPRA, last modified on: 27/04/2015 http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=58746194306-23

88. Meetings of Cabinet members of Commissioner Vytenis Andriukaitis, ibid. 06/02/2015 Brussels, meeting with Hill and Knowlton re. Immuno-oncology treatments, *ibid.*

89. TR: Hill and Knowlton, last modified on: 23/04/2015, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=3183894853-03

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95. CEO and HAI, Divide & Conquer, *ibid.*

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97. DG RTD Health Directorate: 12-13/03/2015, Vaccines Europe, GlaxoSmithKline Vaccines, Novartis Vaccines, Sanofi pasteur, Fraunhoher IME, Takeda, Janseen, Sclavo Vaccines Association, Pfizer.
DG SANTE, 2015.02.13 Unit C3 Health threats, Vaccines Europe; 28.01.2015 Unit D2 – Healthcare Systems,

Vaccines Europe, 2015.02.24 Unit D5 – medicinal products, authorisations and European Medicines Agency, EBE.
According to DG RTD and DG SANTE responses to A2D requests, *ibid.*

98. EFPIA, Membership, *ibid.* NB. In its TR entry, EFPIA states it has 42 corporate members, but on its website lists only 40, and in its 2013 Annual Report states it has 40 corporate members, thus we have gone with this number. EFPIA, 2013 Annual Report, http://www.efpia-annualreview.eu/uploads/documents/EFPIA-AR-2014.pdf p.37

99. Missing corporate members (full) Almirall, Astellas, Boehringer Ingelheim, Chiesi, Daiichi Sankyo, Menarini, Orion Pharma, Takeda, (affiliate) Bial, Esteve, Recordati, The Medicines Company, Vifor Pharma. Based on searching TR on 11/05/15.

100. Full member associations present in the TR are Italy's Associazione delle Imprese del farmaco (FARMINDUSTRIA) Germany's Verband Forschender Arzneimittelhersteller e.V. (vfa), Belgium's Algemene vereniging van de Geneesmiddelenindustrie (pharma.be), Austria's Fachverband der chemischen Industrie (FV Chemie) and France's Les entreprises du médicament (Leem), based on searching TR on 11/05/15. None of the other 28 member associations listed at http://www.efpia.eu/about-us/membership could be found in TR as of 11/05/15.

101. DG RTD Directorate E 'HEALTH' meetings with pharma reps, Date: 25/02/2015; Location: Brussels; Entity/(ies): EFPIA, GSK, AbbVie, Almirall, AstraZeneca, Bayer, Biogen Idec, Boehringer Ingelheim, GSK, Janssen, MSD, Novartis, Novo Nordisk, Pfizer, Sanofi Pasteur, UCB, Vifor Pharma; Subject: IMI2 JU.
According to DG RTD response to A2D request GestDem 2015/1628, released under code of good administrative behaviour, *ibid.*

102. DG SANTE meetings with pharma reps, Date: 2015.3.16, Name of DG SANTE Unit: Unit D1 – Strategy and international, Unit D5 – Medicinal products - authorisations, European Medicines Agency Unit D6 – Medicinal products – quality, safety and efficacy, Principal Advisor to the DDG; Organisation met: EFPIA (European Federation of Pharmaceutical Industries and Associations), APRaD (Association of Pharmaceutical Research and Development), Subject matter discussed: Presentation by EFPIA and APRaD on medicines situation in the Ukraine and their activities there. Short exchange of views of possibilities for DG SANTE to provide help in Ukraine.
According to DG SANTE response to A2D request GestDem 2015/1729, *ibid.*

103. CEO, Towards legalised corporate secrecy in the EU? April 27th 2015, http://corporateeurope.org/power-lobbies/2015/04/towards-legalised-corporate-secrecy-eu

104. EFPIA, EuropaBio, ECPA, Letter to Catherine Day, Subject: Meeting request re. Implementation of EU legislation on public access to documents, 7 March 2015, http://corporateeurope.org/sites/default/files/attachments/letter_europabio_and_al_to_cath._day_7_march_2014_redacted.pdf

105. Catherine Day, Letter to EFPIA, EuropaBio, ECPA, Subject: Access to documents and the protection of commercial interest/Intellectual property, Ref. Ares(2014)4121614 – 09/12/2014, http://corporateeurope.org/sites/default/files/attachments/letter_cd_sg_to_europa_bio_ares_850462_23.03.2014_redacted.pdf

106. DG SANTE Health Directorate meetings with pharma reps. DG SANTE Directorate Health systems and products, 2015.03.10 Phone call with EFPIA Director, and 11.03.2015 meeting with EFPIA. Meetings with DG SANTE Unit D1 – Strategy and international, 2014.11.17, 2014.11.20 (together with Sanofi and Bayer), 2015.3.16 (together with APRaD, plus units from EMA). DG SANTE Unit D3 – eHealth and Health Technology Assessment, 2014.12.01 Phone call with EFPIA Director, and meetings with EFPIA 2014.12.17, 2015.02.24 (together with HTA), 2015.02.26 (together with HTA). Meetings with DG SANTE Unit D5 – medicinal products, authorisations and EMA, 2014.11.05, 2014.12.09, 2014.12.12, 2015.02.16. Meetings with DG SANTE Unit D6 – Medicinal products: Quality, Safety and Efficacy, 2014.12.16 (together with GIRP, EAEPC, PGEU), 2015.01.15, and 2015.03.09 (plus EMA/ 2 Member State representatives).
According to DG SANTE response to A2D request (GestDem 2015/1729), ibid.

107. *ibid.*

108. 11.03.2015, DG SANTE Unit D2 – Healthcare Systems, Head of Unit and 2 staff members, meeting with EFPIA re. Follow up of the meeting with Commissioner Andriukaitis. ibid.

109. Meetings of Commissioner Vytenis Andriukaitis with organisations and self-employed individuals, http://ec.europa.eu/transparencyinitiative/meetings/meeting.do?host=a980459e-c697-49b1-9713-5c5034a26cdc&d-6679426-p=3, as of 22/05/15. The most recent meeting listed is 24/03/2015 and therefore after the meeting of DG SANTE's Healthcare systems unit on 11/03/2015.

110. DG GROW meetings with pharma reps, 3/11/2014 IMI 2 Governing Board Meeting DG ENTR/F; 10/02/2015 Meeting with Mr J. Jimenez, new President EFPIA DG GROW/I; 25/02/2015 EFPIA, EGA, EuropaBio DG GROW/I/3; 09/03/2015 EFPIA, DG GROW/I and I/3.
According to DG GROW response to A2D request Ref GestDem 2015/1652, ibid.

111. DG TRADE meetings with pharma reps, 05/12/2014, Meeting with EFPIA; 22/01/2015, Meeting with EFPIA on the topic of Inter-Association Joint Russia Strategy Session. Based on information released to Rachel Tansey by DG TRADE following A2D request GestDem 2015/1658, info received 20-21/05/15 under the code of good administrative behaviour.

112. Meetings of Cabinet members of Commissioner Cecilia Malmström with organisations and self-employed individuals, http://ec.europa.eu/transparencyinitiative/meetings/meeting.do?host=61aa8586-2b0d-4394-b196-30c13f1fa663&d-6679426-p=15, as of 24/04/2015. 25/02/2015, Brussels, European Federation of Pharmaceutical Industries and Associations, re. Trade negotiations and health; 10/02/2015, Brussels, European Federation of Pharmaceutical Industries and Associations, re. TTIP

113. DG RTD Health Directorate meetings with pharma reps. EFPIA meetings re. IMI2 JU: 03/11/2014, 04/11/2014, 18/11/2014, 18/11/2014, 26/11/2014 (together with Thermo Fisher Scientific, Janssen, Johnson & Johnson (J&J), Abbott Vascular, Novo Nordisk, Imidia, Sanofi, Bayer Pharma, Lilly, Novartis), 01/12/2014, 10/12/2014, 11/12/2014, 05/01/2015, 13/01/2015 ,15/01/2015, 23/01/2015 (together with AstraZeneca, GSK, J&J, Lundbeck, UCB), 27/01/2015, 30/01/2015, 03/02/2015, 04/02/2015, 06/02/201513/02/2015, 20/02/2015, 25/02/2015, 25/02/2015 (together with GSK, AbbVie, Almirall, AstraZeneca, Bayer, Biogen Idec, Boehringer Ingelheim, GSK, Janssen, MSD, Novartis,

Novo Nordisk, Pfizer, Sanofi Pasteur, UCB, Vifor Pharma), 27/02/2015, 04/03/2015, 05/03/2015, 12/03/2015. Other EFPIA meetings: 23/01/2015 re. Antimicrobial resistance; 28/01/2015 and 02/02/2015 re. COMBACTE project; 04/02/2015 Debate: 'The Access to Medicine Index'; 03/03/2015 re. Ebola - "From Emergency to Recovery" (Ebola Private Sector Mobilisation Group, EFPIA, Fondation/Institut Mérieux, GlaxoSmithKline, J&J, Merck; 11/03/2015 re. Data Privacy.
According to DG RTD response to A2D request (GestDem 2015/1628), info released under code of good administrative behaviour, ibid.

114. Meetings of Commissioner Carlos Moedas with organisations and self-employed individuals http://ec.europa.eu/transparencyinitiative/meetings/meeting.do?host=375218b1-5b9b-4f1f-8701-cda656622c9a, as of as of 24/04/2015.
23/01/2015, Davos, Novartis International AG, Bilateral meeting the CEO of Novartis & EFPIA President

115. Meetings of Cabinet members of Commissioner Carlos Moedas with organisations and self-employed individuals, http://ec.europa.eu/transparencyinitiative/meetings/meeting.do?host=39401b95-74dc-4360-8ce2-aca281bc-05c1&d-6679426-p=4, as of as of 24/04/2015.
10/02/2015, Brussels, EFPIA re. Science and innovation, and 9/12/2014, Brussels, EFPIA re. Innovative Medicines Initiative / Ebola crisis.

116. EFPIA, The Power of One: a commitment to collaboration, 2013 Annual Review and forward look, http://www.efpia-annualreview.eu/uploads/documents/EFPIA-AR-2014.pdf

117. EFPIA, The power of one: *ibid.*

118. IMI, http://www.imi.europa.eu/

119. IMI http://www.imi.europa.eu/content/mission

120. *Spiegel Online*, The People Pay, Corporations Cash In: Problems Plague EU Medical Research Initiative, April 01, 2015, http://www.spiegel.de/international/europe/imi-in-eu-project-citizens-count-corporations-cash-in-a-1025550.html

121. *Spiegel Online*, Conflict 1: A Growing Gap Between Essential Medicines and Profitable Fields of Business, *ibid.*

122. Archived page: EFPIA, IMI, https://web.archive.org/web/20111023095832/http://www.efpia.eu/Content/Default.asp?PageID=515
As noted in *Spiegel Online*, *ibid.*

123. *Spiegel Online*, Conflict 3: A Lack of Transparency, http://www.spiegel.de/international/imi-transparency-not-really-a-1025577.html

124. *Spiegel Online*, Conflict 2: Inadequate Monitoring, http://www.spiegel.de/international/imi-inadequate-monitoring-in-eu-project-a-1025569.html

125. IMI, Mission, http://www.imi.europa.eu/content/mission

126. *Spiegel Online*, Conflict 4: IMI Research Diverges from WHO Goals, http://www.spiegel.de/international/business/imi-research-diverges-from-who-goals-a-1025572.html

127. EUPATI, Home, http://www.patientsacademy.eu/index.php/en/

128. *According to EPF's 2013 Acknowledgement of financial support, of its EPF's total €1.29 million income in 2013, more than half a million euros came from big pharma (€506,768 or 39.2%).* http://www.eu-patient.eu/About-EPF/Transparency/Support/epf-acknowledgement-of-financial-support-2013/

129. Quote from David Hammerstein, TACD, in *Spiegel Online*, Conflict 5: Patients Are Becoming Lobbyists for the Industry, http://www.spiegel.de/international/business/imi-controversial-eupati-project-trains-patient-representatives-a-1025563.html

130. Quote from Anke Steckelberg, University of Hamburg and member of IMI's Project Advisory Board, in *Spiegel Online*, Conflict 5, ibid.

131. Euractiv, Scientists shun medicines project amid funding row, 07/09/2010, http://www.euractiv.com/innovation-enterprise/scientists-shun-medicines-projec-news-497511

132. Letter from the League of European Research Universities (LERU) to the IMI board, the member states representatives (SRG), and the IMI IP working group, LERU Letter on the Innovative Medicines Initiative (IMI), 03 September 2010, http://www.leru.org/files/general/LERU_Letter%20on%20IMI_2010%2009%2002.pdf

133. LERU, *ibid.*

134. According to Michael Browne, head of European Research and Development at University College, London, as reported in: Gunjan Sinha, Spat over IMI funding and intellectual property, *Nature Biotechnology* 29, 473 (2011)doi:10.1038/nbt0611-473a, 07 June 2011, http://www.nature.com/nbt/journal/v29/n6/full/nbt0611-473a.html

135. As noted by Viola Johnson from BIO Germany, quoted in in *Spiegel Online*, Conflict 6: IMI Rules Come With Hitches, http://www.spiegel.de/international/business/a-1025556.html

136. Christian Jager from the University of Freiberg, Germany, office for EU relations, quoted in *Spiegel Online*, Conflict 6, *ibid.*

137. EFPIA, The power of one: A Commitment to collaboration. 2013 Annual Review and forward look, http://www.efpia-annualreview.eu/uploads/documents/EFPIA-AR-2014.pdf

138. *Spiegel Online*, Conflict 6, *ibid.*

139. EFPIA , EFPIA's Commission Briefing Paper 2014-2019 Legislature, 24 September 2014, http://www.efpia.eu/uploads/Modules/Documents/efpia%27s-briefing-paper-september-2014-new-com-structure.pdf

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141. TTIP: A Civil Society Response to the Big Pharma wish list, *ibid*.

142. TTIP: A Civil Society Response to the Big Pharma wish list, *ibid.*

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145. Brody H and Light DW (2011) The Inverse Benefit Law: How Drug Marketing Undermines Patient Safety and Public Health, Am J Public Health;101: 399–404. doi:10.2105/AJPH. 2010.19984.

146. Trading Health? UK Faculty of Public Health Policy Report on the Transatlantic Trade and Investment Partnership, Chapter five: Intellectual property – access to medicines, 2015, http://www.fph.org.uk/uploads/FPH%20Policy%20report%20on%20the%20Transatlantic%20Trade%20and%20Investment%20Report%20-%20FINAL.pdf

147. EPHA et al, The inclusion of investor-to-state dispute settlement (ISDS) in Transatlantic Trade and Investment Partnership (TTIP) would undermine public health, 2014, http://bit.ly/1BxgnIt

148. HAI Europe, Protecting citizens' health: Transparency of clinical trial data on medicines in the EU, October 2013, http://haieurope.org/wp-content/uploads/2013/10/HAI_Protecting-citizenshealth-transparency-of-clinical-trial-data-on-medicines-in-the-EU.pdf

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152. Document released to CEO under A2D laws. Ref. Ares(2015)1147176 – 16/03/2015, Meeting with Pfizer 4 November 2013.

153. Document released to CEO under A2D laws. Internal DG TRADE email, Subject: Meeting with BCTT on TTIP IPR issues – 4 October 2013; Sent: October 10 2013.

154. Eli Lilly listed as a client bringing a revenue of 25,000 € - 49,999 € in 2013. Transparency Register, Fleishman-Hillard, last modified on: 27/04/2015, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=56047191389-84, accessed 27/04/15

155. Lilly's CEO John Lechleiter said TTIP "should be comprehensive and ambitious, addressing regulatory harmonisation, intellectual property market provisions... and public procurement measures" plus "set ambitious goals on regulatory harmonisation aspects, including mutual recognition and clinical trials". Document released to CEO under A2D laws. Internal DG TRADE email, Subject: Meeting Lilly 4 March; Sent: March 08, 2013.

156. Document released to CEO under A2D laws. Internal DG TRADE email, Subject: TTIP Pharma – Meeting with Eli Lilly; Sent: November 21, 2013.

157. Document released to CEO under A2D laws. Meeting with the German Pharmaceutical Industry Association (BPI), 5 December 2013.

158. Document released to CEO under A2D laws. Internal DG TRADE emails, Subject: meeting with EFPIA of 25 September; Sent Sept 26 2012; and, Subject: HLWG; regulatory issues; pharmaceuticals; meeting with EFPIA on 26 Nov; Sent Nov 28 2012.
Meeting with EFPIA on TTIP Regulatory issues, 9 December 2013.

159. Document released to CEO under A2D laws, Ref. Ares(2015)1147176 – 16/03/2015, Meeting with EFPIA on innovation and TTIP, 18 June 2014

160. Document released to CEO under under A2D laws. Meeting with EFPIA on TTIP Regulatory issues, 19 February 2014

161. Document released to CEO under A2D laws. Powerpoint presentation, EFPIA and PhRMA: TTIP - An Opportunity to Increase Regulatory Compatibility in the Biopharmaceutical Sector EU-U.S. High Level Regulatory Cooperation Forum, April 10, 2013.

162. Document released to CEO under A2D laws. Meeting with industry on EU-US FTA IPR Chapter, 17 April 2014, Summary.

163. European Commission, List of Lead Negotiators for the Transatlantic Trade and Investment Partnership (TTIP), 05/03/2015, http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151668.pdf

164. Cecilia Malmström's correspondence – letters and e-mails – sent to or received from organisations, companies, ministries and individuals acting in an official capacity, http://ec.europa.eu/commission/2014-2019/malmstrom/correspondence_en 11 results found when "pharmaceutical" was searched on 23/04/15.

165. 10/02/2015 EFPIA "TTIP" meeting, 25/02/2015 EFPIA "Trade negotiations and health" meeting. Meetings of Cabinet members of Commissioner Cecilia Malmström with organisations and self-employed individuals, http://ec.europa.eu/transparencyinitiative/meetings/meeting.do?host=61aa8586-2b0d-4394-b196-30c13f1fa663&d-6679426-p=15, as of 24/04/15.

166. Access to documents request to DG SANTE made by Rachel Tansey on 19/03/2015 (Ref GestDem No 2015/1729), and subsequent exchanges with DG SANTE of 25/03/2015 and 26/03/2015 (Ares(2015)1339599), for a"list of meetings between pharmaceutical industry representatives (eg pharmaceutical companies, trade associations or lobby consultancies/law firms representing the interests of pharmaceutical companies or their trade associations) and officials/staff below the level of Director General, in Directorate General Health and Food Safety's (DG SANTE) Directorate A (Units A1 and A2 only), Directorate C (Unis C1, C2, C3 and C4) and Directorate D (Units D1, D2, D3, D4, D5 and D6) from 1/11/2014 to 19/03/2015". List received on 15/04/15 including Date of meeting, Name of DG SANTE Unit, SANTE Staff, Organisation met and Subject matter discussed.

167. 04/03/2015 Medtronic, Medical device and TTIP meeting, ibid.

168. Cabinet Malmström, 17/01/2014, Document Ares(2014)102329, RE, Invitation to Commissioner Malmström, http://ec.europa.eu/carol/index-iframe.cfm?fuseaction=download&documentId=090166e5951507a5&title=email.pdf

169. Cabinet Malmström, 27/01/2015, Document Ares(2015)315962, INVITATION: ROUNDTABLE EVENT INVITE: Thursday 5 March 2015 - ECIPE/Alliance for Healthcare Competitiveness, http://ec.europa.eu/carol/index-iframe.cfm?fuseaction=download&documentId=090166e59c678d78&title=email.pdf

170. Alliance for Healthcare Competitiveness, Members, http://healthcare-competitiveness.com/our-members/

171. TR: ECIPE, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=78900211516 8-26 last modified 30/01/2015

172. Alliance for Healthcare Competitiveness listed as a client bringing revenue below 9,999 € in financial year 07/2013 – 06/2014. Transparency Register, Edelman Public Relations Worldwide, last modified on: 23/04/2015, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=68037017809-51

173. AHC, TTIP Stakeholder Forum, October 1, 2014, http://healthcare-competitiveness.com/wp-content/uploads/AHC-TTIP-Testimony-October1.pdf

174. Cabinet Malmström, 12/12/2014, document ares(2014)4236787, Request for a meeting in Davos 21 to 24 January 2015, Novartis, http://ec.europa.eu/carol/

index-iframe.cfm?fuseaction=download&documentId=090166e59bb55c7f&title=JIMENEZ_Joseph%20-%20MAIN.pdf and 13/01/2015, Document Ares(2015)133180, Reply - Request for a meeting in Davos Ares(2014)4236787, http://ec.europa.eu/carol/index-iframe.cfm?fuseaction=download&documentId=090166e59c1ca0ea&title=e-mail.pdf

175. Estimate of the annual costs related to activities covered by the register:1,500,000 € - 1,999,999 € in financial year 12/2013 - 12/2014. Transparency Register, Novartis, last modified on: 24/04/2015, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=91269481588-28 accessed on 27/04/15.

176. Novartis listed as a client bringing in a revenue of 10,000 € - 24,999 € in 2014. Transparency Register, acumen public affairs, last modified on: 03/04/2015, http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=85679286747-21 accessed on 27/04/15.

177. Unknown if the invitation was accepted, for although the document replying to VCI's invitation is referred to in the Commissioner's online disclosure, the file in question cannot be opened (as of 14/08/15). See: Cabinet Malmström, 09/12/2014, Document Ares(2014)4126051, Reply/ Invitation for the 6 of May 2015 VCI Parliamentary Reception and a meeting request concerning the chemcial-pharmaceutical industry, http://ec.europa.eu/carol/? fuseaction=detail&department=ca.26&recordsPerPage=10&searchString=&fullText=1&fromRegistrationDate=&tillRegistrationDate=&documentId=080166e59b8702db

178. Cabinet Malmström, 19/11/2014, Document Ares (2014)3923560, Invitation for the 6 Of May 2015 VCI Parliamentary Reception and a Meeting Request Concerning the Chemical-Pharmaceutical Industry, Verband Der Chemischen Industrie E.V., http://ec.europa.eu/carol/index-iframe.cfm?fuseaction=download&documentId=090166e59b2d06ee&title=DEKKERS_Marijn.pdf

179. *Public Affairs News*, Full steam ahead, 4 April 2014, https://www.publicaffairsnews.com/articles/analysis/full-steam-ahead

180. *Public Affairs News*, Full steam ahead, *ibid.*

181. CEO, Tobacco lobbyists all fired up ahead of key vote, July 8th 2013, http://corporateeurope.org/lobbycracy/2013/07/tobacco-lobbyists-all-fired-ahead-key-vote

182. Access to documents request by Neil Mclaren, 5 December 2013, to DG SANCO, for 'Both incoming and outgoing digital correspondence between SANCO representatives and both Tobacco & Pharmaceutical industry lobbyists & lawyers between July 2013 - December 2013', GESTDEM No.2013/6192. Request and DG SANCO response, including annex of documents, available at http://www.asktheeu.org/en/request/sanco_correspondence_with_indust#incoming-4147

183. Annex 1 to A2D request GESTDEM No.2013/6192, *ibid,* AESGP E-mail on Minutes meeting 06/05/2013 (including annex), http://www.asktheeu.org/en/request/1067/response/4145/attach/html/5/Annex%201.pdf.html

184. See, eg *The Times*, E-cigarettes can be gateway to tobacco, warns rival Glaxo, February 17 2014,http://www.thetimes.co.uk/tto/business/industries/health/article4007244.ece; Bloomberg, Glaxo Memo Shows Drug Industry Lobbying on E-Cigarettes, February 19, 2014, http://www.bloomberg.com/news/articles/2014-02-19/glaxo-memo-shows-drug-industry-lobbying-on-e-cigarettes

185. The correspondence between the Commission's DG SANCO and tobacco and pharmaceutical industry lobbyists and lawyers, between July 2013 and December 2013, released in response to the access to documents request which revealed both the AESGP and GSK correspondence, showed the majority of correspondence to be with the tobacco industry.


CEO