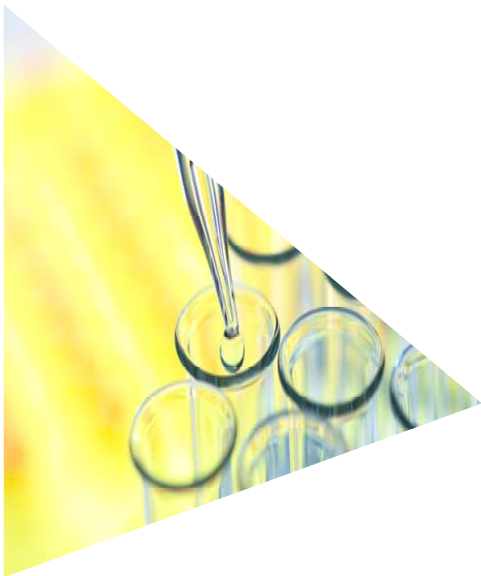


Transparency in the relationship between HCPs and the Pharmaceutical Industry : European perspective



Apifarma Conference
Lisbon, 14 December 2016

George Fife, Partner, EY



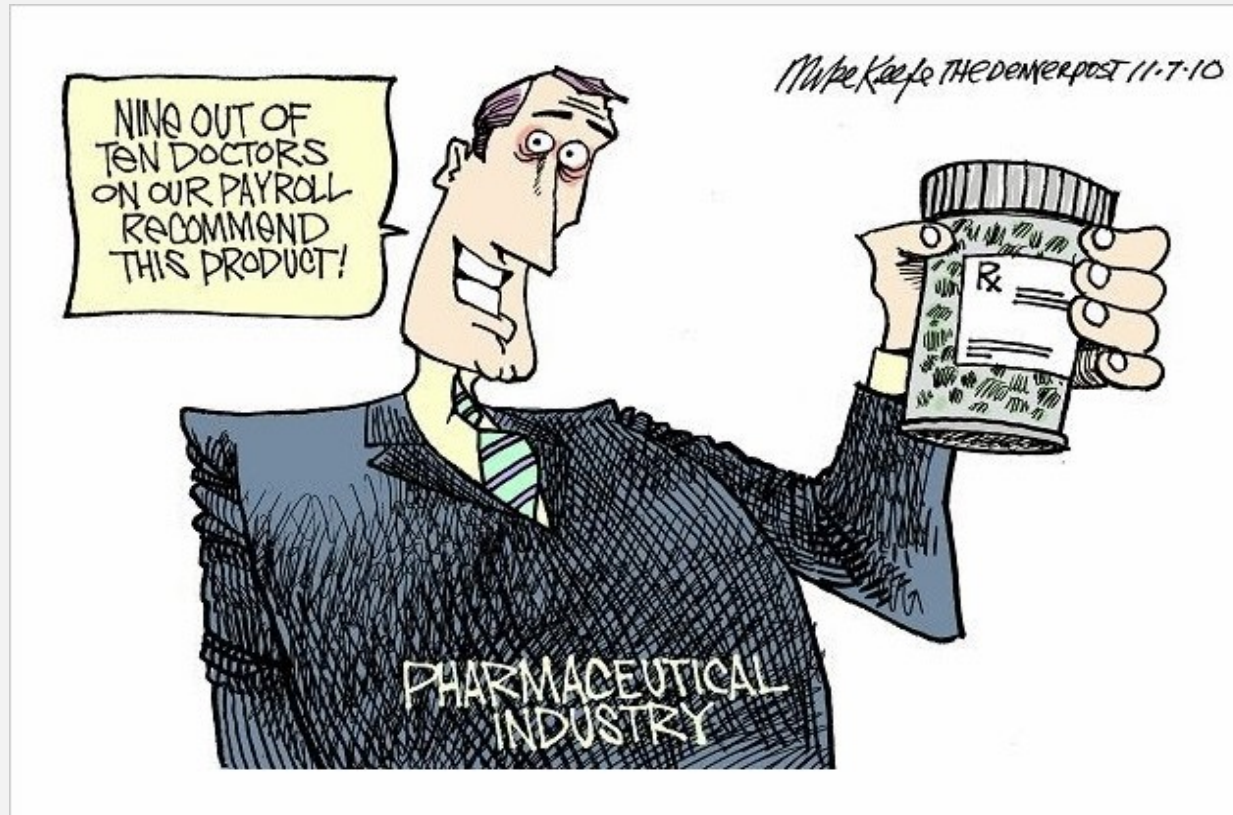
Everything starts with Patients Perspectives

“The Corporate Reputation of Pharma – The Patient Perspective”, 2014 Survey *

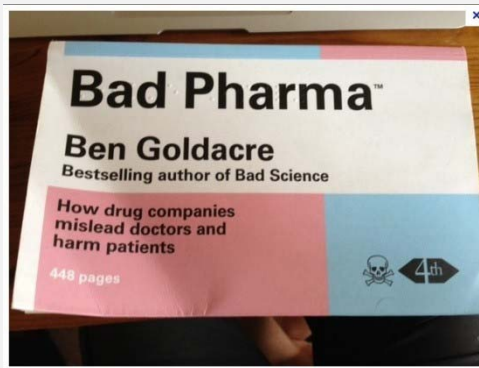
- ▶ **Patient groups regard pharma more positively in 2014 than they did in 2013:** 26% of the patient groups responding say that the industry's corporate reputation has improved (against 18.9% saying the same in 2013).
- ▶ **Mixed emotions** about aspects of pharma: from the **hope engendered** in patients by a number of important new clinical trials, to the disbelief that reimbursement **authorities refuse** to approve some of pharma's latest products **on the grounds of the high prices** set by the companies.
- ▶ **The lowest ratings awarded relate to the ability (or otherwise) of pharma companies to implement fair pricing policies.** As many as 43.4% of the 550 respondent Europe-based patient groups think pharma poor at pricing products fairly.
- ▶ Comments offered by the respondent Europe-based patient groups show that areas of distrust between patient groups and pharma include the following:
 - ▶ **pharma corruption scandals,**
 - ▶ **litigation against pharma;**
 - ▶ the possibility that **health professionals may be in the pocket of the industry;**
 - ▶ **absence of robust science** when presenting clinical data;
 - ▶ lack of **patient access to expensive new drugs;**
 - ▶ excessive profitmaking;
 - ▶ and ... not taking patients' needs and viewpoints into consideration.

* *Source: PatientView Survey 2014 - 550 Respondents – 70% European based*

Reality or Perception



Changing attitude and expectation of stakeholders?



PHARMALOT

Pharma industry has more in common with Martin Shkreli than it likes to admit

The New York Times JAN. 18, 2016

Even Talking About Reducing Drug Prices Can Reduce Drug Prices

A Critical Relationship

- ▶ Collaboration between industry and health professionals benefits patients. It is a relationship that has delivered numerous innovative medicines and treatments and changed the way many diseases impact on our lives. Industry and health professionals collaborate in a range of activities from clinical research to sharing best clinical practice and exchanging information on how new medicines fit into the patient pathway.
- ▶ HCPs are relied upon as **partners** to the pharmaceutical industry. Yet, recent disruption with high-profile criticism of the industry by HCPs impacts on the quality of the long-standing collaboration, which (may) undermine(s) trust in the pharmaceutical industry, also in the HCP community.
- ▶ At the same time, the industry finds increasing failures in public authorities' (and even HCPs') recognition / acknowledgment of the role of R&D-based companies in the scientific advances and the development of new treatments.
- ▶ **Creeping mistrust could ultimately lead to skepticism about the value of new and innovative therapies.** Regaining trust and HCPs' esteem for R&D-based industry's contribution to improved health outcomes is essential to ensure that the industry-healthcare profession relationship operates to the best benefit of patients.

Source: EFPIA – IPCAA presentation '16

Where is Pharma Industry going

- ▶ The R&D-based pharmaceutical industry is committed to working in partnership with all stakeholders to improve healthcare across Europe. The creation of new or improved medicines relies upon the collaboration between healthcare professionals and the pharmaceutical industry
- ▶ Industry is conscious of the importance of providing accurate, fair and objective information about its medicines to allow rational decisions to be made about their use
- ▶ In the same spirit, industry is committed to working towards greater transparency, accountability and ethical behaviour within an industry framework of self-regulation, which has been successful in protecting clinical independence but the expectations are increasing and we need to keep up with these
- ▶ Therefore, EFPIA will continue to develop additional guidance around areas where industry's credibility is engaged

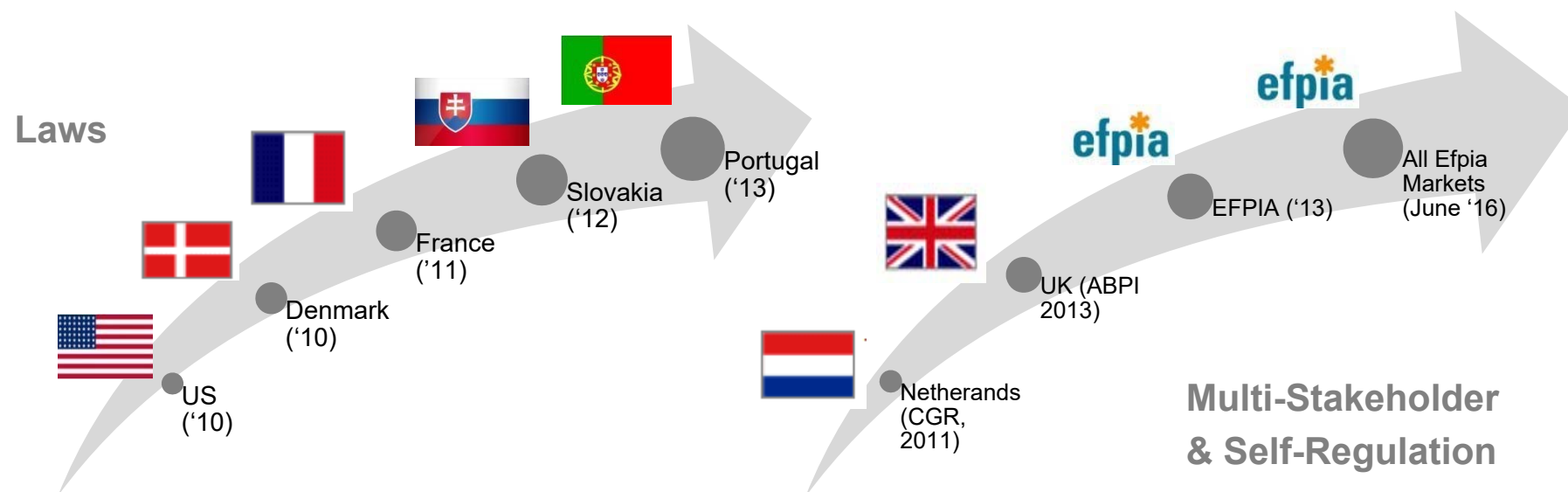
Source: EFPIA – IPCAA presentation '16

Transparency - What was already enforced not to forget (not exhaustive)

- ▶ Promotional Materials
 - ▶ Communication/approval/notification prior use / after use to authorities or physician councils
- ▶ Activities or Consulting Services:
 - ▶ Notification or pre-approval
 - ▶ Belgium: Visa MDEON
 - ▶ France: physician council (CnoM) & Health Authorities (HAS)
 - ▶ Greece: EOF
 - ▶ Norway: Radet (National Drug information Council)
 - ▶ Spain: FarmaIndustria Deontological Supervision Unit (USD)
 - ▶ France: disclosure to Health Authorities
 - ▶ HCP declarations of interests to Health Authorities (EMA, HAS,...)
- ▶ Employer pre-approvals :
 - ▶ Germany, Italy, Sweden, Turkey, France & Greece (for certain typologies of HCPs)
- ▶ Relationships with Patient Advocacy Groups (EFPIA Code) – 2012 public disclosures
- ▶ Research & Development: Clinicaltrials.gov
- ▶ Fiscal Declarations

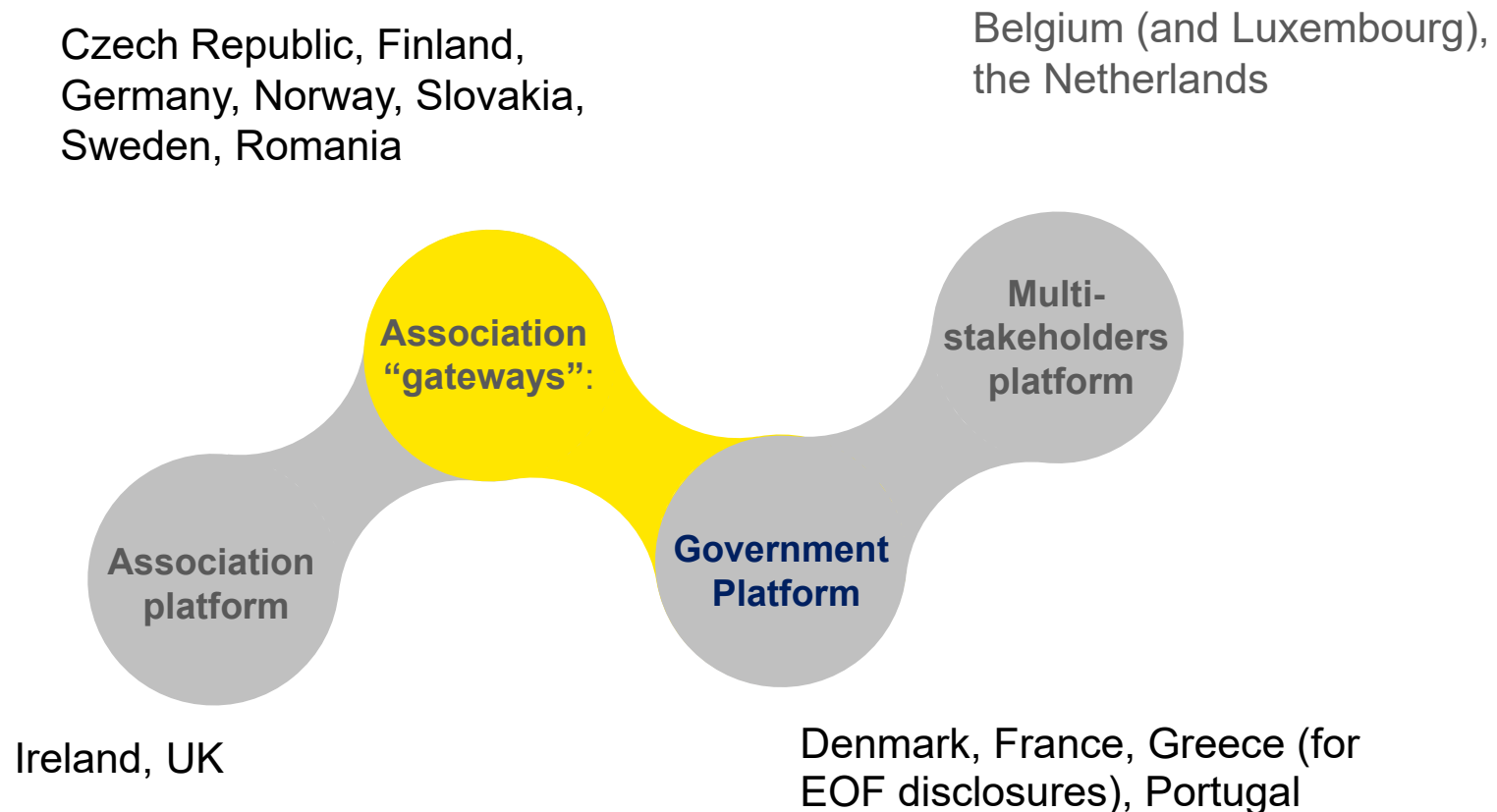
Emergence of Global Transparency on transfer of values

- ▶ A number of Laws and Industry Codes have been enacted increasing collection and global reporting requirements
- ▶ Requirements all rotate with the same spirit around transfer of value disclosures – but vary in scope and format
- ▶ Every indication is that this trend will continue – lack of consistency and disclosure comprehension by general public emerge as issue
- ▶ EFPIA go-live in June '16 and upcoming new legislations underway (Greece, Slovakia)
- ▶ Now approx 12 Countries have or are considering to enact transparency-related laws (incl. Romania, Estonia, Latvia, Lithuania, Serbia,...)



Scattered publication panorama : Websites, gateways, central platforms

Several types of “**Central Platforms**” have been implemented :



Access to Disclosed Transfer of Value

SWEDEN: LIF's Gateway to companies disclosures

Link to the portal/database:
<http://www.lif.se/etik/samarbetsdatabaser/?type=Disclosure>



Novartis Sverige AB	2015	Värdeöverföringar Metodnotering Metodnotering – Engelsk
Novo Nordisk Scandinavia AB	2015	Länk till värdeöverföringar
Octapharma AB	2015	Värdeöverföringar Värdeöverföringar - Engelsk Metodnotering
Orion Pharma AB	2015	Värdeöverföringar Metodnotering

Access to Disclosed Transfer of Value

UK: ABPI Searchable central platform

Member Association searchable platform:
<http://www.abpi.org.uk/media-centre/newsreleases/2016>



Database available to download on the ABPI website (www.disclosureuk.org.uk), showing payments from 109 pharmaceutical companies in the UK (54 ABPI member companies and 55 non-member companies).

Search the database



Click here to search the database

Download data

As well as searching Disclosure UK you can also download the full dataset.

To download the data you must acknowledge that you accept the terms and conditions below.

Downloaded data should be read in conjunction with the *Guidance notes for analysis of the data* and the methodological notes.

Access to Disclosed Transfer of Value Belgium: Mdeon Platform (co-regulation)

Multi-stakeholders platform (managed by Mdeon):
<https://www.betransparent.be/en/>



To **CONSULT THE REGISTER**, click [HERE](#).

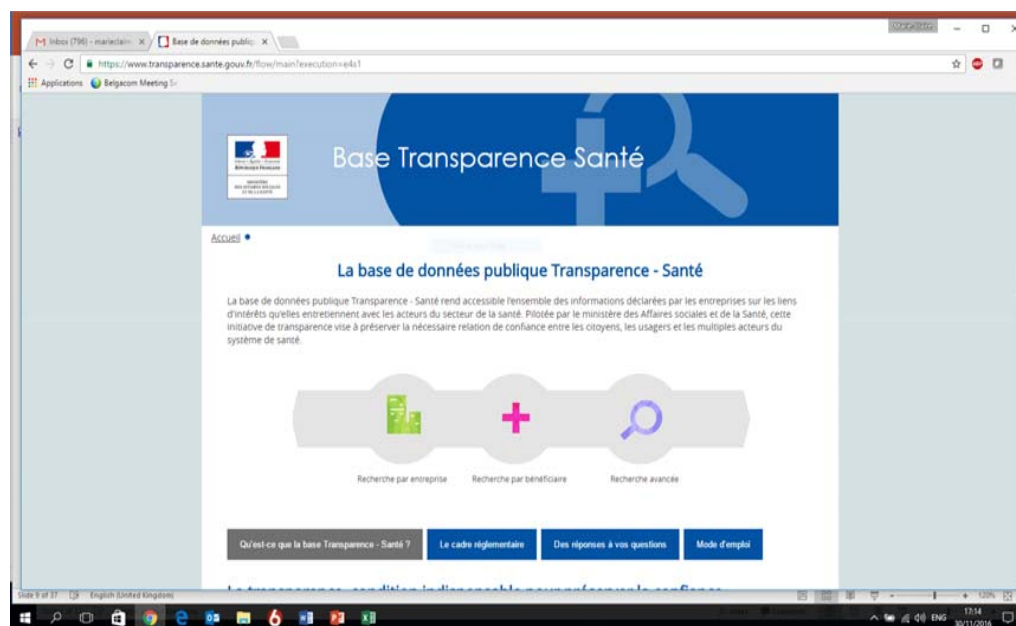
Search by:

- Healthcare professional (physician, pharmacist, nurse, etc.)
Name or INAMI Number
- Healthcare organization (hospital, scientific association, incorporated professional, etc.)
Enterprise Number or Official Name
- Pharmaceutical or medical devices company
VAT Number or Official Name

Following copy of CAPTCHA, access to data

Access to Disclosed Transfer of Value France: Governmental Platform

<https://www.data.gouv.fr/fr/datasets/transparence-sante-1/>



Utilisation des données

Conformément au II bis de l'article L. 1453-1 du code de la santé publique, les informations publiées sur ce site internet sont **réutilisables, à titre gratuit, dans le respect de la finalité de transparence des liens d'intérêts** et dans les conditions prévues aux articles L. 321-1, L. 321-2, L. 322-1 et L. 322-2 du code des relations entre le public et l'administration.

La réutilisation des informations est soumise au respect de la licence de réutilisation et des dispositions de la loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés.

Access to Disclosed Transfer of Value Spain: Company websites

ESPAÑA - ESPAÑOL

SELECCIONE UN PAÍS

TRANSPARENCIA Y COLABORACIONES

ACERCA DENOSOTROS

INVESTIGACIÓN E INNOVACIÓN

CARRERA

PRODUCTOS

TRANSPARENCIA Y COLABORACIONES

AbbVie está comprometida en colaborar estrechamente con profesionales sanitarios, organizaciones sanitarias y organizaciones de pacientes para mejorar la salud de los pacientes en toda Europa y en el mundo. La información intercambiada en estas relaciones ha llevado a nuevos y mejores tratamientos y, lo que es más importante, a una mejor asistencia a los pacientes.

Creemos que las interacciones con profesionales sanitarios, organizaciones sanitarias y organizaciones de pacientes aportan valor a la asistencia a pacientes. Nuestras colaboraciones están guiadas por la apertura y la transparencia, con el objetivo de proporcionar al público mayor confianza.

AbbVie ha aportado detalles de estas relaciones con organizaciones de pacientes desde 2.010 en España.

Además, AbbVie ha declarado detalles de colaboraciones con profesionales sanitarios en EE. UU. desde marzo de 2012, además de en varios países europeos.


Desde el 30 de junio de 2016, AbbVie comienza a declarar detalles de sus relaciones con profesionales sanitarios y organizaciones sanitarias en España y en toda Europa.

AbbVie está comprometida en colaborar estrechamente con profesionales sanitarios, organizaciones sanitarias y organizaciones de pacientes para mejorar la salud de los pacientes en toda Europa y en el mundo. La información intercambiada en estas relaciones ha llevado a nuevos y mejores tratamientos y, lo que es más importante, a una mejor asistencia a los pacientes.

TRANSPARENCIA Y COLABORACIONES

RELACIONES CON ORGANIZACIONES DE PACIENTES

RELACIONES CON PROFESIONALES SANITARIOS Y ORGANIZACIONES SANITARIAS

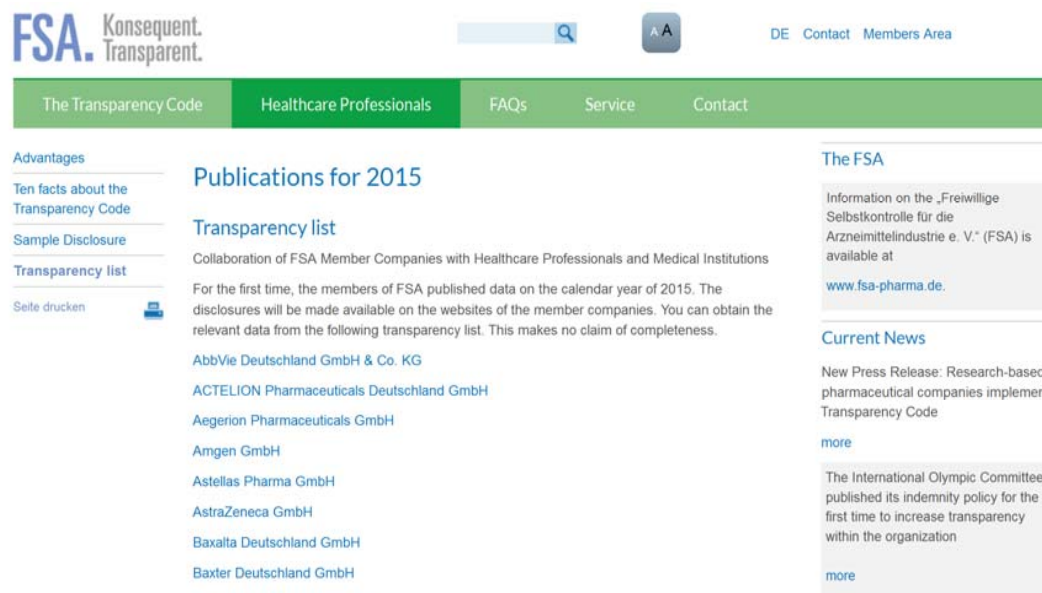


Data as of: 06/30/2019									
Transparency Report 2019 (Table 1)									
Indicador	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)			Prestación de servicios (Art. 15.2.3.a y 15.2.3.b)			TOTAL		
Art. 15.2.3.a	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)
Art. 15.2.3.a	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)	Actividades, servicios y productos ofrecidos por el profesional (Art. 15.2.3.a y 15.2.3.b)
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Access to Disclosed Transfer of Value Germany - FSA's Gateway to companies disclosures

Link to the portal/database:

<http://www.pharma-transparency.eu/members-of-the-healthcare-profession/transparency-list/>



The screenshot shows the FSA (Freiwillige Selbstkontrolle der Arzneimittelindustrie e.V.) website. The header includes the FSA logo with the tagline "Konsequent. Transparent." and navigation links for "DE", "Contact", and "Members Area". A green navigation bar contains links for "The Transparency Code", "Healthcare Professionals", "FAQs", "Service", and "Contact". The main content area is titled "Publications for 2015" and "Transparency list". It states that for the first time, members of FSA published data on the calendar year of 2015. A list of member companies is provided, including AbbVie Deutschland GmbH & Co. KG, ACTELION Pharmaceuticals Deutschland GmbH, Aegerion Pharmaceuticals GmbH, Amgen GmbH, Astellas Pharma GmbH, AstraZeneca GmbH, Baxalta Deutschland GmbH, and Baxter Deutschland GmbH. The right sidebar contains sections for "The FSA" and "Current News".

German Media

14 July 2016

Database of Spiegel Online and Correctiv.org was
published

SPIEGEL ONLINE

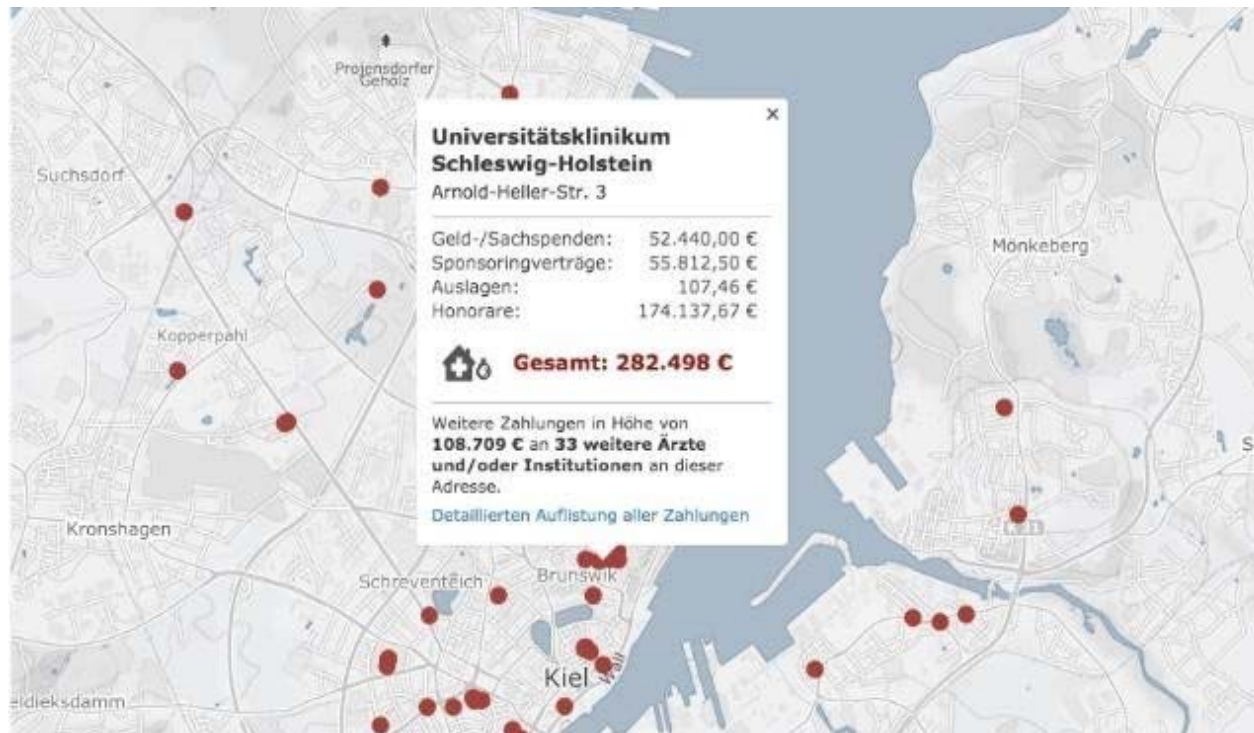


German Media

Pharmahonorar für Ärzte

Vielen Dank für die Millionen!

Rund 71.000 Ärzte erhielten 2015 Geld von der Pharmaindustrie, die Verstrickungen sind fragwürdig. **SPIEGEL ONLINE** und **"Correct!v"** haben eine Datenbank erstellt, mit der Sie Ihren Arzt suchen können.



CORRECT!V



Finde Deinen Arzt

Wieviel Geld hat Dein Arzt/Heilberufler im vergangenen Jahr von der Pharmaindustrie erhalten? Die 54 größten Pharma-Unternehmen in Deutschland veröffentlichen im Jahr 2016 erstmals alle Geldzahlungen, die sie im vergangenen Jahr an Ärzte, Fachkreisangehörige und Kliniken geleistet haben. [Zum Hintergrundartikel](#)

Pharmakonzerne zeigen sich gern großzügig gegenüber Ärzten: Sie bezahlen sie für Vorträge, laden sie zu Kongressen ein, erstatten ihnen Hotelübernachtungen, honorieren sie für Anwendungsbeobachtungen. 575 Millionen Euro flossen auf diese Weise im vergangenen Jahr an mehr als 71.000 Ärzte und medizinische Einrichtungen in Deutschland. Nur 20.000 Ärzte sind aber einverstanden, dass ihr Name veröffentlicht wird.

Top-Ärzte mit bekannten Zahlungen

Hans-Christoph Diener	200.193,64 €
Jürgen Rockstroh	148.413,95 €
Michael Albrecht Nauck	123.165,79 €
Thomas Forst	99.973,96 €
Mathias Mäurer	95.686,21 €

Top-Pharmafirmen

Novartis Pharma GmbH	91.052.175,69 €
Merck KGaA	55.870.206,76 €
Roche Pharma AG	46.348.985,00 €
Bayer AG	33.579.514,76 €
MSD Sharp & Dohme GmbH	31.152.344,40 €

In conclusion...

- 1 Continued enforcement is likely to continue on life sciences, with more CIAs and DPAs issued
- 2 Trust & Reputation remains paramount – Promoting Ethics & Transparency to become the standard
- 3 Data privacy & Legitimate Interest
- 4 Secondary Use of Transparency data
- 5 How to be *really* transparent - Central Platforms...no central platforms...the right balance
- 6 Foster Scientific Legitimate Exchange and role of pharma
- 7 Transparency convergence - Life Science industries: innovative pharmaceuticals, OTC, Medical Devices, Generics, Cosmetics,...but also HCO's, HCPs, PAG,...

Foster today's individual behavior...

*« INTEGRITY is doing the right thing even
when nobody is watching »*

CS Lewis

George Fife | Partner

FIDS – Business Integrity & Corporate Compliance
Life-Sciences

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