

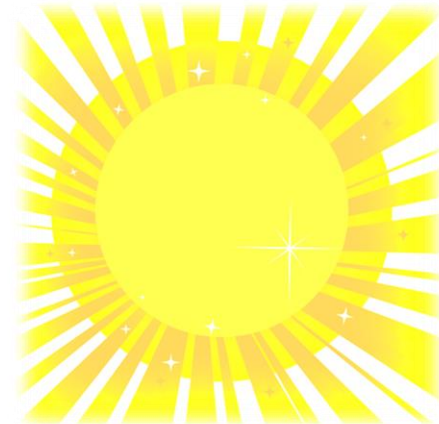
# Transparency & Disclosure Reporting

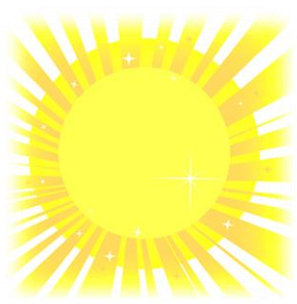
Ricardo Moreno, MD, CCEP  
Brian P. Sharkey



Seton Hall University – Latin America Healthcare Compliance  
Certification Program  
Buenos Aires, Argentina  
September 28, 2017

# Terminology

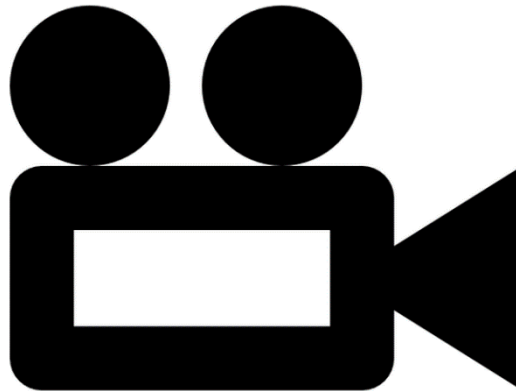




“Disclosure brings about accountability, and accountability will strengthen the credibility of medical research, the marketing of ideas and, ultimately, the practice of medicine. The lack of transparency regarding payments made by the pharmaceutical and medical device community to physicians has created a culture that this law should begin to change substantially. The reform represented by the Grassley–Kohl Sunshine Law is in patients’ best interests.” – *Senator Charles Grassley*, co-author of the Sunshine Act



# Why Transparency is Important?



Duration: 45 seconds

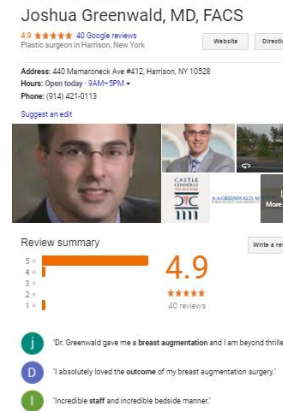
# Types of Transparency in Healthcare

## Hospitals to HCIs

- Cost Transparency reports
- Price Transparency reports
- Adverse Events



Leilani Schweitzer is shown in this undated photo with her son, Gabriel. (Leilani Schweitzer)



## Patients to Patients

- Healthcare Portals
- Patient Surveys
- Patient Networks

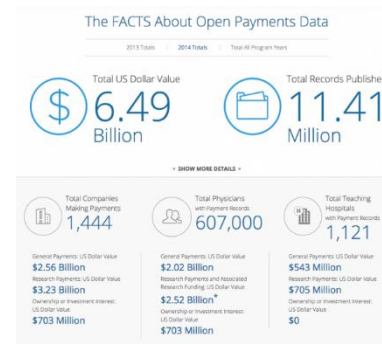
Interactions



Patients

## HCPs to HCPs

- Metrics
- HCPs Networks
- Medical Associations



## Manufactures to GOs

- Sunshine Act
- Open Payments
- Industry Associations (Self Regulation)





Medicare

Medicaid/CHIP

Medicare-Medicaid  
Coordination

Private  
Insurance

Innovation  
Center

Regulations &  
Guidance

Research, Statistics,  
Data & Systems

Outreach &  
Education

Home > Open Payments > Program Participants > Physicians and Teaching Hospitals > Review and Dispute

Open Payments

About

Explore the Data

Program  
Participants

FAQs

Contact Us

### Program Participants

Applicable Manufacturers and GPOs  
Physicians and Teaching Hospitals  
Events  
[Sign Up or Log Into the EIDM Portal](#)

### Physicians and Teaching Hospitals

Physicians and Teaching Hospitals: HOME  
Registration  
[Review and Dispute](#)  
Resources for Physicians & Teaching Hospitals  
General Resources  
Help Desk / Contact Us  
Explore the Data  
Registration Information for Physician Authorized Representatives

## Review and Dispute for Physicians and Teaching Hospitals

### After June 30, can I dispute incorrect data in the Open Payments system?

Yes, you have until the end of the calendar year, in which the data is first published, to review and dispute the reported information. Changes that drug or device companies make to the data (as a result of your dispute) will be seen publicly in the data refresh (usually occurring in January of the next year).

- *Data can only be disputed in the year it is first published.* For example, a 2015 record published on June 30, 2016 can only be disputed until December 31, 2016.
- *New data may be published from any previous program year.* For example, a 2013 record published on June 30, 2016 can only be disputed until December 31, 2016.

Check your data annually to make sure you don't miss a chance to review older data also.

**Already registered?** Go direct to the [CMS portal](#) to review.

**Need to Register?** Visit the [registration information](#) page to start.

**Need help reviewing data or are you part of the office team?** Use the [quick reference guide](#) to nominate team members to help.



## OpenPaymentsData.CMS.gov

About Sign In

# Find Your Doctor's Payments

First Name

Last Name

[Search](#)

[Explore Open Payments Data](#)

Looking for a [teaching hospital](#) or [company making payments](#)?

For a more refined search, use the [Search Tool](#).

[How to use the Search Tool](#)

[Check out the new Payments by State page](#)

## The Facts on Open Payments

[See Summary Data](#)

[See Payments by State page](#)

2013  
Totals

2014  
Totals

2015  
Totals

2016  
Totals

Totals All  
Years



Total US Dollar Value  
**8.18 BILLION**



Total Records Published  
**11.96 MILLION**

## The Facts on Open Payments

[See Summary Data](#)

[See Payments by State page](#)



Total US Dollar Value  
**24.94 BILLION**



Total Records Published  
**40.77 MILLION**

# Dollars for Docs

By Charles Ornstein, Lena Groeger, Mike Tigas, and Ryann Grochowski Jones, ProPublica. Updated December 13, 2016

Pharmaceutical and medical device companies are now required by law to release details of their payments to a variety of doctors and U.S. teaching hospitals for promotional talks, research and consulting, among other categories. Use this tool to search for general payments (excluding research and ownership interests) made from August 2013 to December 2015. | [Related Story: We've Updated Dollars for Docs. Here's What's New.](#) »

## Has Your Doctor Received Drug or Device Company Money?

 All States   
 Search

For example: Andrew Jones, Boston, 10013

**\$6.25B** in disclosed payments **810,716** doctors **1,171** teaching hospitals **1,866** companies

### About the Dollars for Docs Data

Details behind our drug company money database.

### Download the Data

The entire data set is available for purchase in the [ProPublica Data Store](#).

### Source

The Centers for Medicare and Medicaid Services [Open Payments](#) data.

### Archive

## Are drug firms paying your doctor? Illinois doctors accepted \$74.1M in industry payments last year



In 2016, doctors in Illinois accepted more than \$74 million from drug companies. (Getty Images)

By **Lisa Schencker** and **Jennifer Smith Richards** · [Contact Reporter](#)  
Chicago Tribune

AUGUST 17, 2017, 1:58 PM



Post Nation

## Study: Doctors received more than \$46 million from drug companies marketing opioids

By **Katie Zezima** August 9



Bottles of medications line the shelves at a pharmacy in Portsmouth, Ohio. (Bryan Woolston/Reuters)

NEW JERSEY REAL-TIME NEWS

## Drug companies doled out \$69 million to N.J. doctors last year

56

Updated on July 6, 2017 at 10:02 AM. Posted on July 6, 2017 at 7:18 AM

f t 1.8k shares

HEALTH AND FITNESS NEWS

## Doctors raked in cash to push fentanyl as N.J. death rate exploded

132

Updated on July 3, 2017 at 11:08 AM. Posted on June 29, 2017 at 7:00 AM



## EFPIA HCP/HCO DISCLOSURE CODE

### EFPIA CODE ON DISCLOSURE OF TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

CONSOLIDATED VERSION 2014  
Approved by the General Assembly of 6 June

GENERAL ASSEMBLY  
06 June 2014 – final editing 11 July 2014

Page 1 of 15

# Year 1: 2016 Reporting on 2015 Data Year 2: 2017 Reporting on 2016 Data

SCHEDULE 2 - TEMPLATE												Date of publication: _____	
	Full Name (Art. 1.01)	HCPs: City of Principal Practice HCOs: city where registered (Art. 3)	Country of Principal Practice (Schedule 1)	Principal Practice Address (Art. 3)	Unique country identifier OPTIONAL (Art. 3)	Donations and Grants to HCOs (Art. 3.01.1.a)	Contribution to costs of Events (Art. 3.01.1.b & 3.01.2.a)			Fee for service and consultancy (Art. 3.01.1.c & 3.01.2.c)		TOTAL OPTIONAL	
							Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accommodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract		
HCPs	INDIVIDUAL NAMED DISCLOSURE - one line per HCP (i.e. all transfers of value during a year for an individual HCP will be summed up: disclosure should be available for the individual recipient or public authorities' consultation only, as appropriate)												
	Dr A					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	Dr B					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	etc.					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
HCOs	Aggregate amount attributable to transfers of value to such Recipients - Art. 3.02												
	Number of Recipients in aggregate disclosure - Art. 3.02						N/A	N/A	Aggregate HCPs number	Aggregate HCPs number	Aggregate HCPs number	Aggregate HCPs number	Optional
	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art. 3.02						N/A	N/A	%	%	%	%	Optional
	INDIVIDUAL NAMED DISCLOSURE - one line per HCO (i.e. all transfers of value during a year for an individual HCO will be summed up: disclosure should be available for the individual recipient or public authorities' consultation only, as appropriate)												
	HCO 1					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Optional	
HCO 2					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Optional		
etc.					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Optional		
R & D	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
	Aggregate amount attributable to transfers of value to such Recipients - Art. 3.02												
	Number of Recipients in aggregate disclosure - Art. 3.02						Aggregate HCOs number	Aggregate HCOs number	Aggregate HCOs number	Aggregate HCOs number	Aggregate HCOs number	Aggregate HCOs number	Optional
	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art. 3.02						%	%	%	%	%	%	Optional
	AGGREGATE DISCLOSURE												
Transfers of Value re Research & Development as defined - Article 3.04 and Schedule 1											TOTAL AMOUNT	OPTIONAL	

latest update: 11 December 2013 v1



## Pharmaceutical companies continue to drive transparency and underline industry investment in Europe's Healthcare

Over the next ten days, pharmaceutical companies will disclose details of collaborations with health professionals (HCPs) and healthcare organisations (HCOs) across Europe

## PRESS RELEASES

Code of Good Practice for the Pharmaceutical Industry > Good Practices

### R&D and training continue to be the basis for collaboration between the pharmaceutical industry and healthcare professionals

For a second year running, the companies adhering to FARMAINDUSTRIA's Transparency Code publish the collaborations with sector agents

Posted in category **News Release** by **Press Office** on 30/06/2017

## Significant increase in healthcare professionals disclosing partnerships with the pharmaceutical industry



Data published today by the ABPI shows a significant increase in the number of healthcare professionals consenting to sharing details of payments for collaborations with the pharmaceutical industry.



## THE PHARMACEUTICAL INDUSTRY'S COOPERATION WITH HEALTHCARE PROFESSIONALS GREW IN 2016 ON

30 MAY

2017

## Transparency Code: The second year

Joint press release of 21 June

- › Within the scope of the Transparency Code, research-based pharmaceutical companies are already publishing services to physicians for the second time
- › The Transparency Code shows that many doctors in Germany are involved in a strong medical research
- › Only the cooperation of pharmaceutical companies and doctors allows medical progress for the benefit of patients

Over 66% of medical professionals in Bulgaria have agreed to disclose their cooperation with pharmaceutical companies under the Transparency Building Trust initiative



The members of the Finnish Pharmaceutical Industry Association spent EUR 32.5 million in cooperation, which is 16% more than in the previous year. Growth is especially important for research and product development.

News

07/03/2017

## The global trend of transparency responds to social expectations

INFARMA has once again published data on the cooperation of pharmaceutical companies with representatives of the medical profession.

In the same way as last year, companies signatories of the Code of Transparency published data on the value and scope of cooperation with medical professionals, including doctors, pharmacists, nurses and midwives, as well as health organizations for 2016. A summary and links to all company reports are available at [www.kodekspilers.com](http://www.kodekspilers.com).

29/06/2017

DISCLOSURE

In 2016, 77 members of pharma.be invested 148.3 million euros in support of scientific research and formation of the Belgian medical community.



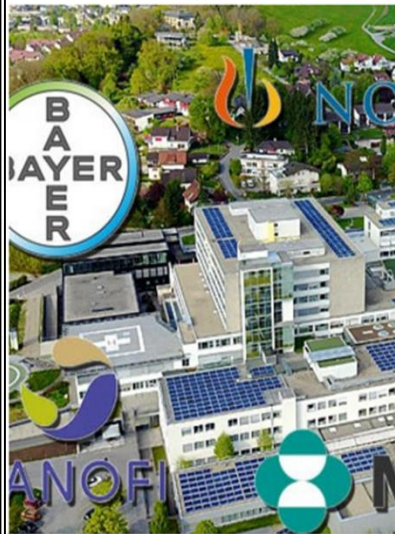
Home » News

**Big pharma cash for hospital hospitality to do one in three ref earnings**



**Vorarlberg's hospit money from the ph**

By Matthias Rauch (VOL.AT) On July:



**ON SUNDAY**

**IRELAND ON SUNDAY**

**DIANA AT WAR**

**Why her dream marriage was doomed within just two years**

**OUR UNMISSABLE SERIES CONTINUES**

**MAGAZINE 10-PAGE SPECIAL**

**Diana and Charles at war**

**PART TWO**

# DRUG FIRMS' SECRET €4.2M TO DOCTORS

Consultants are among thousands who refuse to be identified

By Michael O'Farrell  
and Craig Hughes

HUNDREDS of doctors and hospital consultants continue to secretly pocket millions in payments from pharmaceutical firms while refusing to allow their names to be made public.

The payments raise vital questions about the potential for conflicts of interest when these doctors are prescribing medications to patients or purchasing drugs for publicly funded hospitals.

This weekend, one mother whose son killed himself and another person weeks after he'd been prescribed anti-depressants spoke of her concerns. Leonie Farrell said: 'If the companies are paying money,

Turn to Page 6

**EXCLUSIVE**

**My cancer battle, by Ronnie Wood**

**I was lucky, it could have been curtains**

**PAGES 8 and 67-70**

**Martens wanted children to testify**

By Catherine Fegan

MOLLY Martens, who is accused of murdering her husband, Jason Corbett, tried to summon his two young children to North Carolina to testify in her defence.

Ms Martens's legal team filed a motion to 'determine the availability' of Jack, 12, and Sarah, 16, to appear at her trial with her co-accused father, Tom.

There were also claims that Jack had been 'coached' to say Ms Martens was afraid of her late husband.

**FULL STORY See Page 5**

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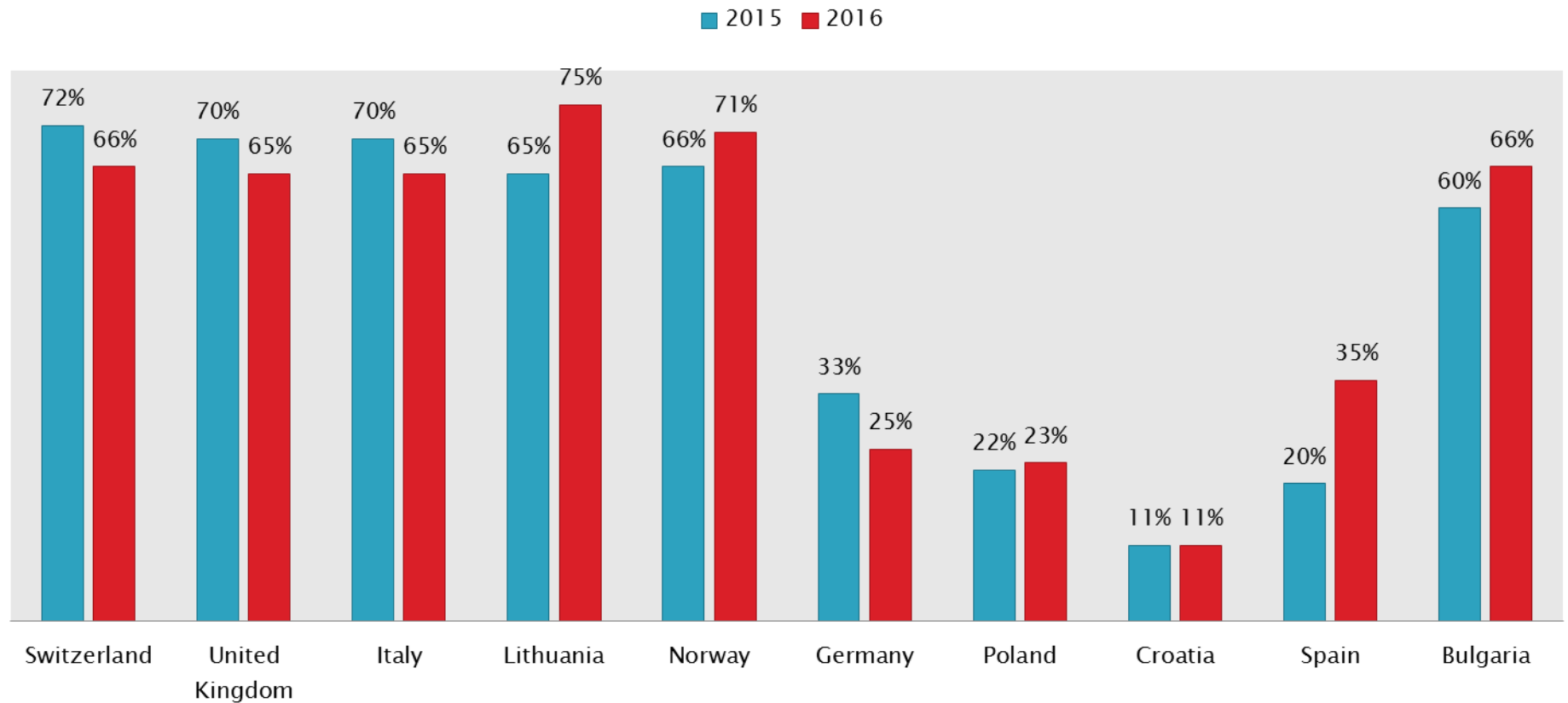


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arma  
IS

# 2015/2016 Reported Consent





# Medicines for Europe



Name of Recipient	Location of the Organisation	Date	Location of the Event	Purpose/Description of the ToV	Expense Details	Aggregated Amount/Value
Ghent University Hospital	Belgium	27 January 2016	London	Educational support, 9th EGA Pharmacovigilance Conference (free entrance included)	one night accommodation, travel	414,25
Bristol Haematology and Oncology Centre	United Kingdom	17 March 2016	Vienna	EGA Satellite Symposium during the 21st Congress of the EAHP	one night accommodation	159
Erasmus University Medical Center	The Netherlands	17 March 2016	Vienna	EGA Satellite Symposium during the 21st Congress of the EAHP (free entrance included)	EAHP congress registration fee	700
European Association of Hospital Pharmacists	Brussels	28 - 29 April 2016	London	14th Annual Biosimilar Medicines Group Conference (free entrance included)	2 nights accommodation, travel	1042,09
St. Antonius Hospitals Utrecht & Nieuwegein	The Netherlands	8-10 June 2016	Dubrovnik	Joint 22 Medicines for Europe- 19th IGBA Annual Conference	1 night accommodation, travel	572,06
Centre Hospitalier Victor Dupouy	France	8-10 June 2016	Dubrovnik	Joint 22 Medicines for Europe- 19th IGBA Annual Conference	1 night accommodation	184,6
<b>Total</b>						<b>3072</b>

CODE

Name of Recipient	Location of the Organisation	Date	Location of the Event	Purpose/Description of the ToV	Expense Details	Aggregated Amount/Value (Euro)
Eurordis	Belgium	27 January 2016	London	Educational support, 9th EGA Pharmacovigilance Conference (free entrance included)	one night accommodation	229,71
European Patient's Forum	Brussels	19 April 2016	Brussels	Universal Access to Health	travel	787,47
EPF Member	Slovakia	28 - 29 April 2016	London	14th Annual Biosimilar Medicines Group Conference (free entrance included)	one night accommodation	295,45
Norwegian IBD Patient Organisation LMF	Norway	28 - 29 April 2016	London	14th Annual Biosimilar Medicines Group Conference (free entrance included)	1 night accommodation, travel	606,45
European Federation of Airways and Allergies Disease	Brussels	8 - 10 June 2016	Dubrovnik	Joint 22 Medicines for Europe- 19th IGBA Annual Conference	1 night accommodation, travel	566,17
European Federation of Neurological Association	Cyprus	31-may-16	Brussels	European Patient's Forum (EPF)	2 nights accommodation, travel, F&B	1292,66
Thalassaemia	Cyprus	31-may-16	Brussels	European Patient's Forum (EPF)	2 nights accommodation, travel	616,58

# MedTech Europe

ANNEX II (added in May 2016)

Disclosure Guidelines Template Example\*

TEMPLATE								
Full HCO Name	HCOs: city where registered	Country of Principal Practice / Activity	Registered Address	Unique country local identifier	A. Educational Grants to Support Third Party Organised Events /or to Support HCP Participation at Third Party Organised Educational Events)	Object (Optional)	B. Other Educational Grants to HCOs (including Scholarships, Fellowships and Grants for Public Awareness Campaigns).	Object (Optional)
HCO/PCO 1					Yearly amount	Optional	Yearly amount	Optional
HCO/PCO 2					Yearly amount	Optional	Yearly amount	Optional
etc.					Yearly amount	Optional	Yearly amount	Optional

\*Please note that this template is for illustrative purposes only. The template to be used for reporting purposes is available in the [TransparentMedTech](#) website.



# Base Transparence Santé

Accueil

## La base de données publique Transparence - Santé

La base de données publique Transparence - Santé est une initiative de transparence vise à préservé le système de santé.



REGISTRO

PÁGINA INICIAL LISTAGEM DO DOMÍNIO PÚBLICO

Comunicações ao INFARMED, I.P., no âmbito do Decreto-Lei n.º 176/2006,

### Listagens do domínio público

Pesquisa

Reche

Pesquisar Limpar

Tipo de Declaração

Medicamentos

Das declarações submetidas na Plataforma de Comunicações - Transparencia e Publicidade

Estas listagens podem ser organizadas por ordem alfabética/valor no sentido ascendente

Lista de Contribuições Declaradas

Lista de Aceitações Declaradas

Ano 2017 Ano 2016 Ano 2015 Ano 2014 Ano 2013

Nome Entidade Contribuinte I <sup>º</sup>	Tipo Dec
medac Sucursal em Portugal	Medicamen
Laboratório Medifar - Produtos Farmacêuticos, S.A.	Medicamen
ITF Farma Produtos Farmacêuticos Lda	Medicamen
Tecnifar-Indústria Técnica Farmacêutica, SA	Medicamen
BGP Products	Medicamen
Tecnifar-Indústria Técnica Farmacêutica, SA	Medicamen
Uilly-Portugal, Produtos Farmacêuticos, Lda	Medicamen
Uilly-Portugal, Produtos Farmacêuticos, Lda	Medicamen

Qu'est-ce que la base Transparence

La transparence, con



## BILLE NA LIA-CHLEACHTÓIRÍ (LEASÚ), 2017 MEDICAL PRACTITIONERS (AMENDMENT) BILL 2017

### Bill

entitled

An Act to require medical practitioners to declare any income or gift received from medical suppliers or pharmaceutical companies to the Medical Council in statutory declaration annually.

Be it enacted by the Oireachtas as follows:

### Definitions

#### 1. In this Act—

“declaimable income” means any money or other form of payment that a medical practitioner receives from a medical equipment supplier, its servants or agents, or pharmaceutical company and its servants or agents above the value of €600;

“gift” means any voluntary transfer of money, grant for research, bursary, service or property without compensation above the value of €600;

“medical equipment supplier” means any company involved in the manufacture and or supply of medical equipment;

“Minister” means the Minister for Health;

“pharmaceutical company” means a company involved in the manufacture, production and or supply of pharmaceutical drugs, creams or other health products which must be prescribed by a medical practitioner;

“Principal Act” means the Medical Practitioners Act 2007; and

“statutory declaration” means a declaration as prescribed under the Statutory Declarations Act 1938.

#### Amendment of section 45 of the Principal Act

#### 2. Section 45 of the Principal Act is amended by the insertion of the following subsections:

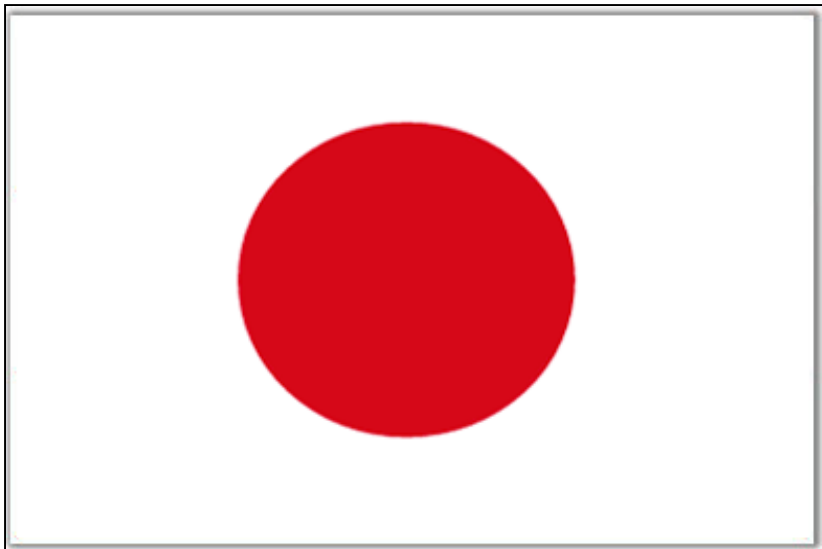
“(8) A registered medical practitioner shall on an annual basis, give to the Medical Council a statutory declaration signed by him or her giving particulars of all declaimable income and gifts received from any medical equipment suppliers, its servants or agents, and or any pharmaceutical companies, its servants or agents, within the previous

REPÚBLICA PORTUGUESA  
SAÚDE



Estado II <sup>º</sup>
Por Validar
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Por Validar



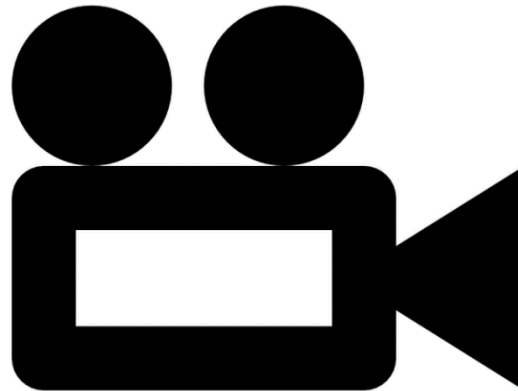




# Purpose



# Purpose



Duration: 1 minute

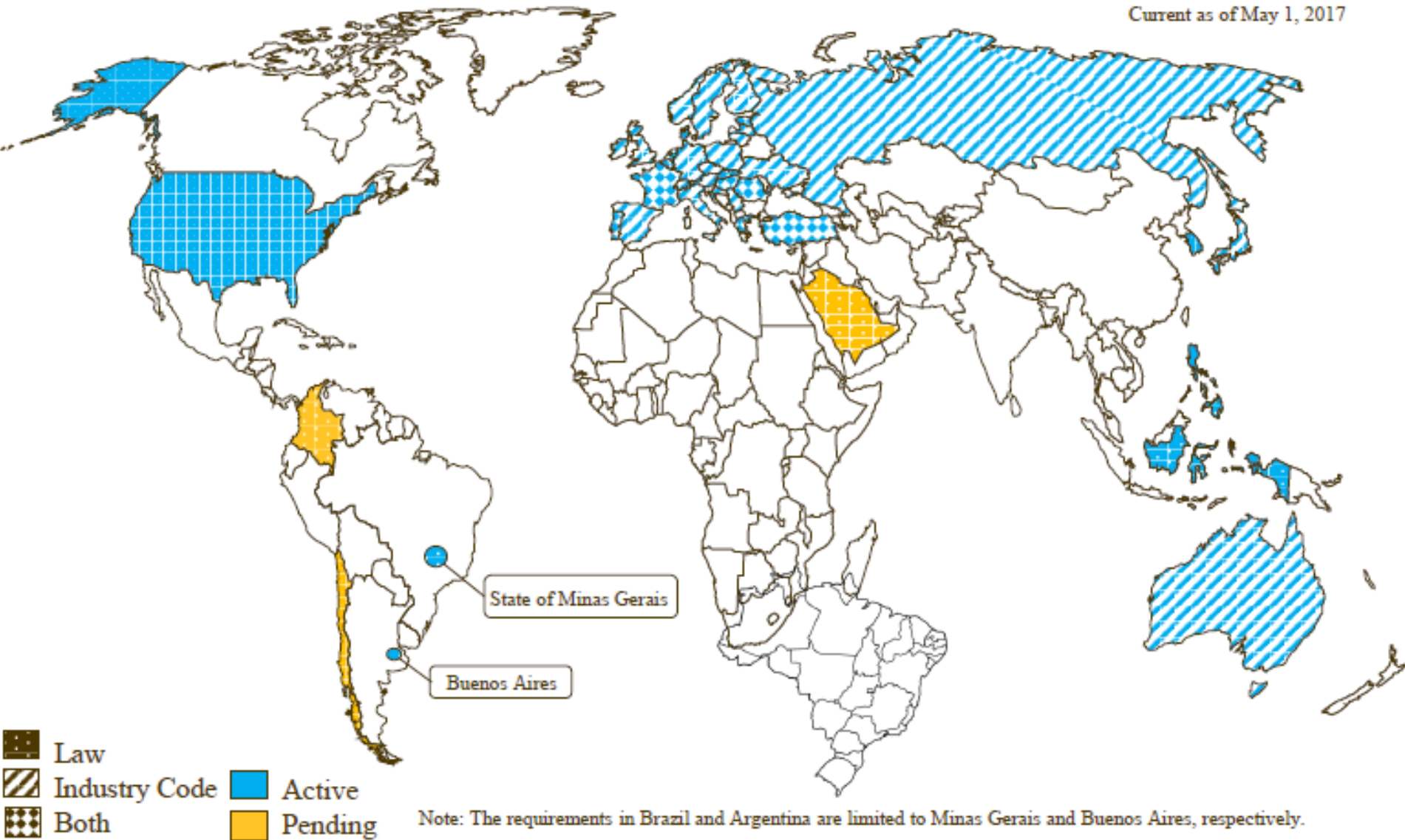
# Purpose

- Sharing information builds trust
- Sustainable trusting Relationships
- Builds mutual accountability of physicians to patients
- Inspires Doctor to do it better
- Is what patients want, need and expect!



# Countries with Disclosure Laws and/or Industry Codes

Current as of May 1, 2017



This presentation is intended for the exclusive use of the International Marketing and Disclosure Compliance Group members and may not be used by any third party



# Brazil (Minas Gerais)



# Brazil (Minas Gerais) Law No. 22440

## **Regulatory Deadline Extension**

- The Action Committee formed by the Minas Gerais Secretary of Health to draft implementing regulations for the state's disclosure law has been granted an extension to issue its recommendations
  - Originally, the Committee was required to issue a report with its recommendations on May 24, 2017
  - On May 22, 2017, the Secretary of Health granted the working group an additional 60 days to complete its review and issue the report
- Once completed, the report will be submitted to the Minas Gerais “Civil House”, which will then promulgate regulations based upon the Committee's recommendations

# Mexico



# Mexico

- The Council of Ethics and Transparency of the Mexican Pharmaceutical Industry (CETIFARMA) issued a fact sheet detailing its voluntary transfer of value disclosure program
- Under the program, companies will be expected to publicly disclose on their websites information about the following types of transactions:
  - Support for training of HCPs
  - Sponsorship of scientific and professional meetings
  - Collaborations on clinical research and development
  - Donations
  - Remuneration for professional services
- All transfers of value related to HCPs or research and development will be reported in the aggregate. Transfers of value provided to organizations will be reported individually.



# Mexico

- A “trial” disclosure will occur on **March 30, 2018**, and will provide information for the last quarter of 2017
  - This information will not be disclosed publicly, but will only be provided to CETIFARMA
- The second round of disclosures will take place on **September 28, 2018**, and will detail the first half of 2018
  - This information will be made publicly available
- Disclosures will be made annually thereafter, on **June 30**, covering information for the prior fiscal year

# Chile



# Chile

- After a delay in the senate, Drug Law II, which among other things will impose disclosure requirements, is moving forward
- The bill has moved out of the Senate Health Committee and will likely be considered by the Senate shortly
- Also in Chile: the Annex to the IFPMA Code of Good Practices issued by the ***Cámara de la Innovación Farmacéutica de Chile A.G.*** – discussed in detail on the previous call – has been formally adopted
- An unofficial translation of the document is available on the International Marketing and Disclosure Compliance Group website

# Colombia





# Colombia

- The Colombia Ministry of Health published a regulatory schedule of activities and ongoing projects for the year 2017
- One of the projects listed in the schedule is revising a draft resolution regarding transactions between HCPs and industry
- The schedule anticipates a public comment period will occur sometime between May and mid-June, and the resolution to be finalized by the end of August
- A draft of the resolution will likely be available shortly

# Argentina



# Argentina

- On December 1, 2016, the City Legislature of Buenos Aires, Argentina, passed Act No. 5709, requiring manufacturers, importers, and distributors of medical, biological and pharmaceutical products to disclose transactions with HCPs which may directly or indirectly influence the HCP's therapeutic decisions
  - Cash payments, payments of professional fees, payments for vocational training, travel expenses, and other items of value (i.e. tickets, gifts, lodging, and meals) are subject to disclosure
- Disclosures must be made to the Buenos Aires Ministry of Health, and must include company and HCP information, nature and valuation of the items offered, and the date of the transaction
- Deadlines and penalties will be set by the Ministry