

4th Annual



Global Transparency Reporting Congress

Determine the True Financial Value of a Transaction

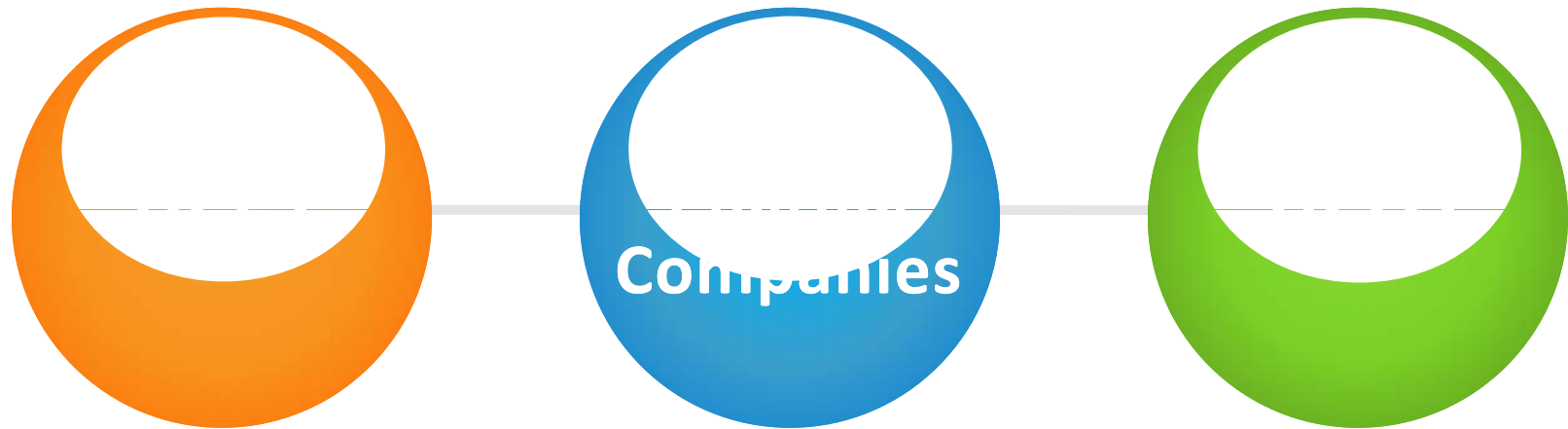
José Ramos, MD
Transformation Manager
Lilly S.A. (Spain)



Introduction

The reason of our interactions is to collaborate in the benefit of our patients

Risk and Realities



HCP and Industry mutually-dependent (complex) relationships ¹

¹ See *CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE* 170-75 (Bernard Lo & Marilyn Field eds., 2008) (documenting these relationships); Eric Campbell et al., *A National Survey of Physician-Industry Relationships*, 356 *NEW ENG. J. MED.* 1742, 1746-47 (2007) (94% of physicians in a recent survey in the United States had some type of relationship with the pharmaceutical industry).

Risks and Realities

HCP and Industry mutually-dependent (complex) relationships ¹

Strengths

⇒ Support

- Research activities
- Covering institutional gaps on:
 - Medical Training
 - CME
 - Information regarding new therapeutic options to benefit patients

Weaknesses

⇒ Bias

- Research and results interpretation
- Medical Training and CME
- Practice guidelines
- Medical treatment decisions

Opportunities

- Auto-regulation
- Transparency

Threats

- Reputational issues
- Public / Institutional budgets constrains

2

¹ See CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 170-75 (Bernard Lo & Marilyn Field eds., 2008) (documenting these relationships); Eric Campbell et al., A National Survey of Physician-Industry Relationships, 356 NEW ENG. J. MED. 1742, 1746-47 (2007)
² Stoltzfus, J.; Oversight of marketing relationships between Physicians and the drug and device industry: a comparative study; American Journal of Law and Medicine, 36 (2010):326-342

Potential options – Preventive strategies

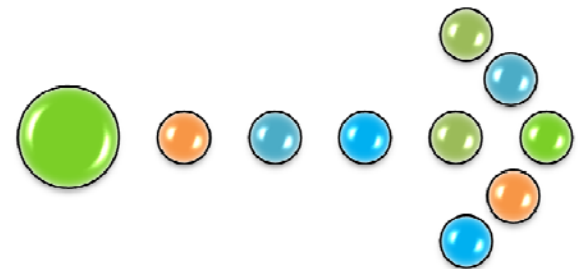
Transparency



Reliable
information



Legitimate need

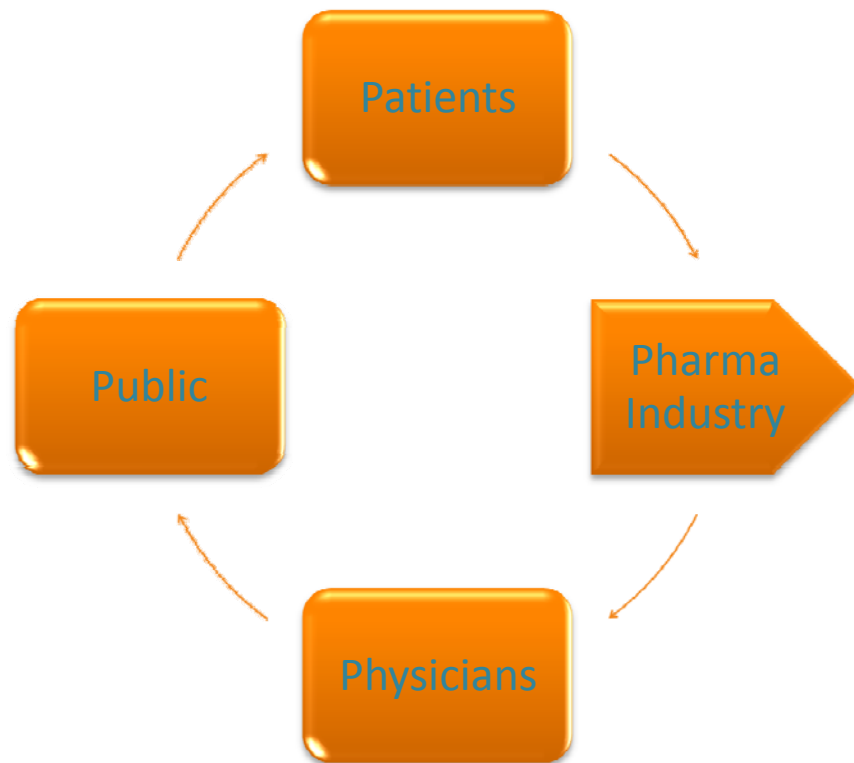




Legitimate need

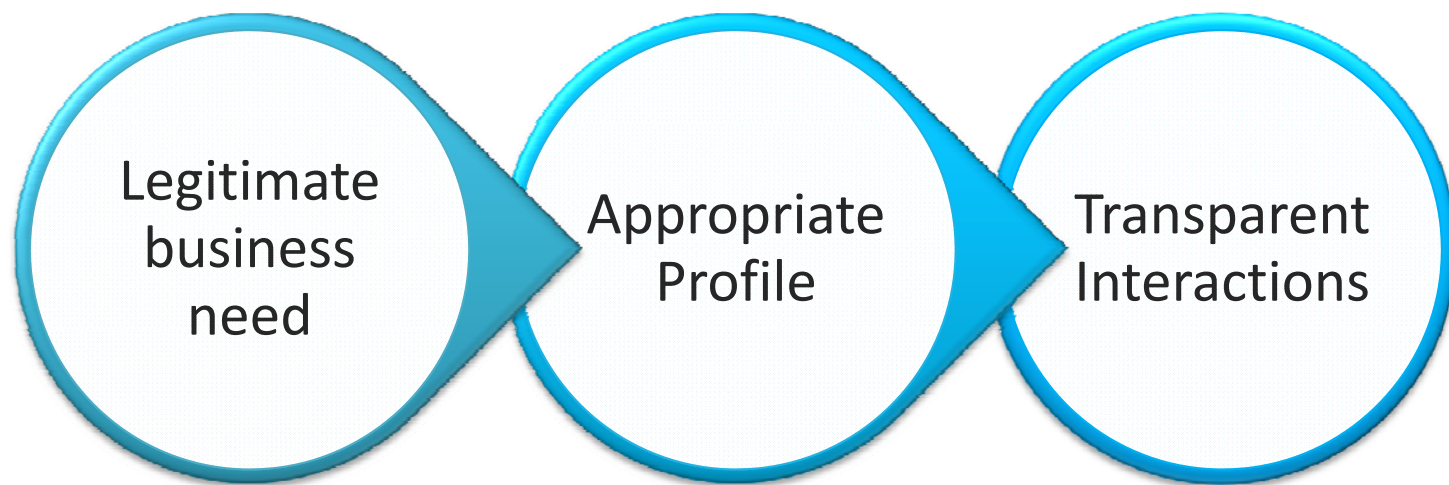
The reason why 

¿Conflict of interest or Efficient virtuous circle?



- Drug research and development
- Conduct Clinical trials to decide drug authorization
- Monitor adverse drug reactions
- Decide on clinical data disclosure
- Provide info on drug benefit/risk
- Support CME
- Collaborate with scientific societies and conferences

Pharma Companies and HCP interactions



Key areas of collaboration between Pharma Companies and HCPs/HCOs



Fee for Services

- Consultanship
- Speaking
- Training
- Other

Support to Medical Education

- Donations
- Grants and benefits in sponsorship of attendance of HCPs at meetings
- Contributions to the cost of medical meetings (including registration fees, accommodation and travel)



Research

- Based on scientific expertise, and achieved results, etc.



Transparency

Nothing else behind 

Transparency...

BASIC PRINCIPLE: "Transparent relationships between Pharma Companies and healthcare professionals who use their products,"

"There's a misperception of the relationships between industry and healthcare professionals,"

Golf outings are not the norm

"Unfortunately, when taken out of context, publicly available information about physician interactions with biopharmaceutical companies does not convey the value of these relationships, which advance science and promote high quality patient care,"

Companies need to consider how they'll manage their relationships with HCPs going forward...

public disclosure impact

"By bringing transparency to the relationships,

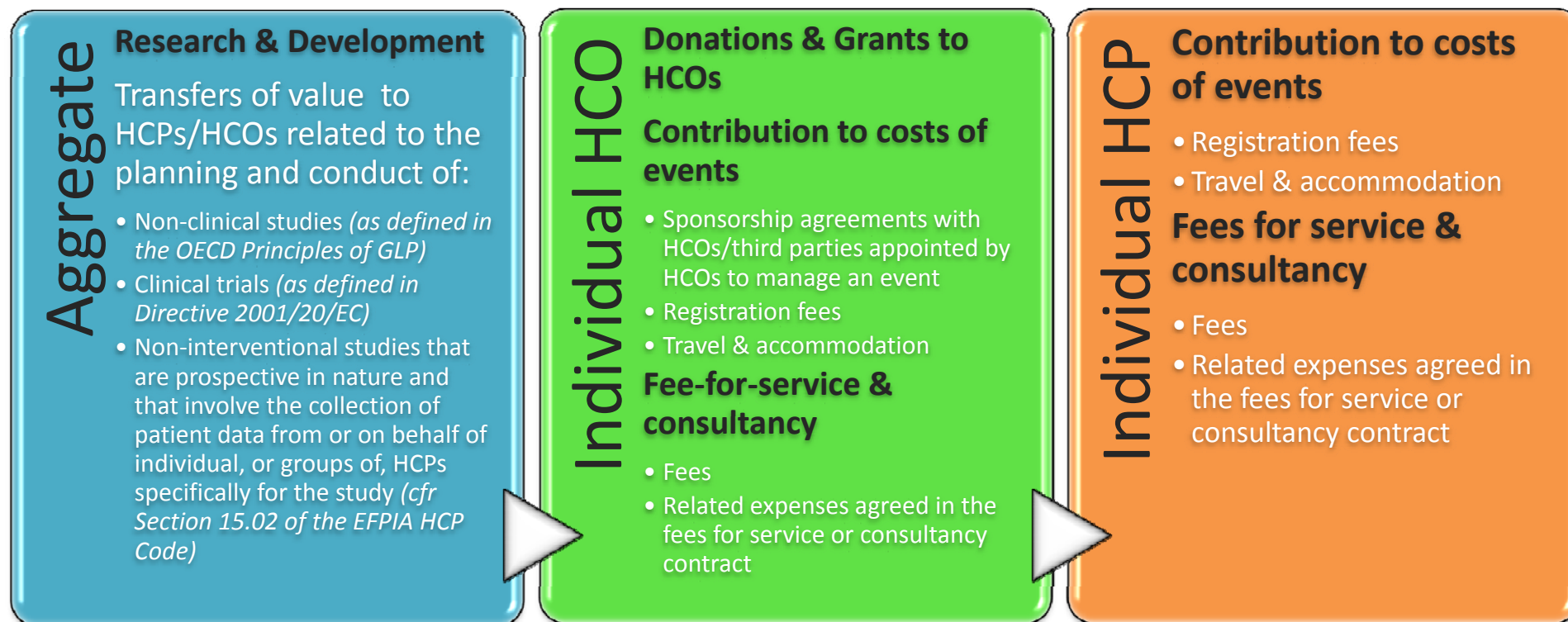
Government, Industry, and Patients can be assured that the relationships are appropriate and serve the mission of improving healthcare

Even if the new code and laws don't achieve that,...

*they will certainly move **the “TRUST METER” up***

EFPIA Transparency Code

Scope of Disclosures



Each company shall publish a note summarising the methodologies used in preparing their disclosures and identifying transfers of value for each category described above (Methodological Note).

Overview of existing laws regarding Transparency across Europe

The Netherlands' Code of Conduct on Transparency of Financial Relations (2012) requires disclosure of aggregate information

The GB Bribery Act prevents bribery while associations like the ABPI and the ABHI set transparency requirements

In Belgium, regulations ensure transparency (internal recordkeeping, Mdeon visa since 2007 etc.)

France is leading the way toward legal regulations with the French Sunshine Act (FSA) enforced in May 2013

In Italy, there are general anti-bribery rules (interdiction of gifts, regulation of hospitality)

In Spain, certain transparency regimes are imposed by the industry associations mostly regarding hospitality

Slovakia has also been a leader in Transparency act by implementing the Slovakia Sunshine Act in September 2011

In Denmark, companies are required to declare their payments to doctor since 2008

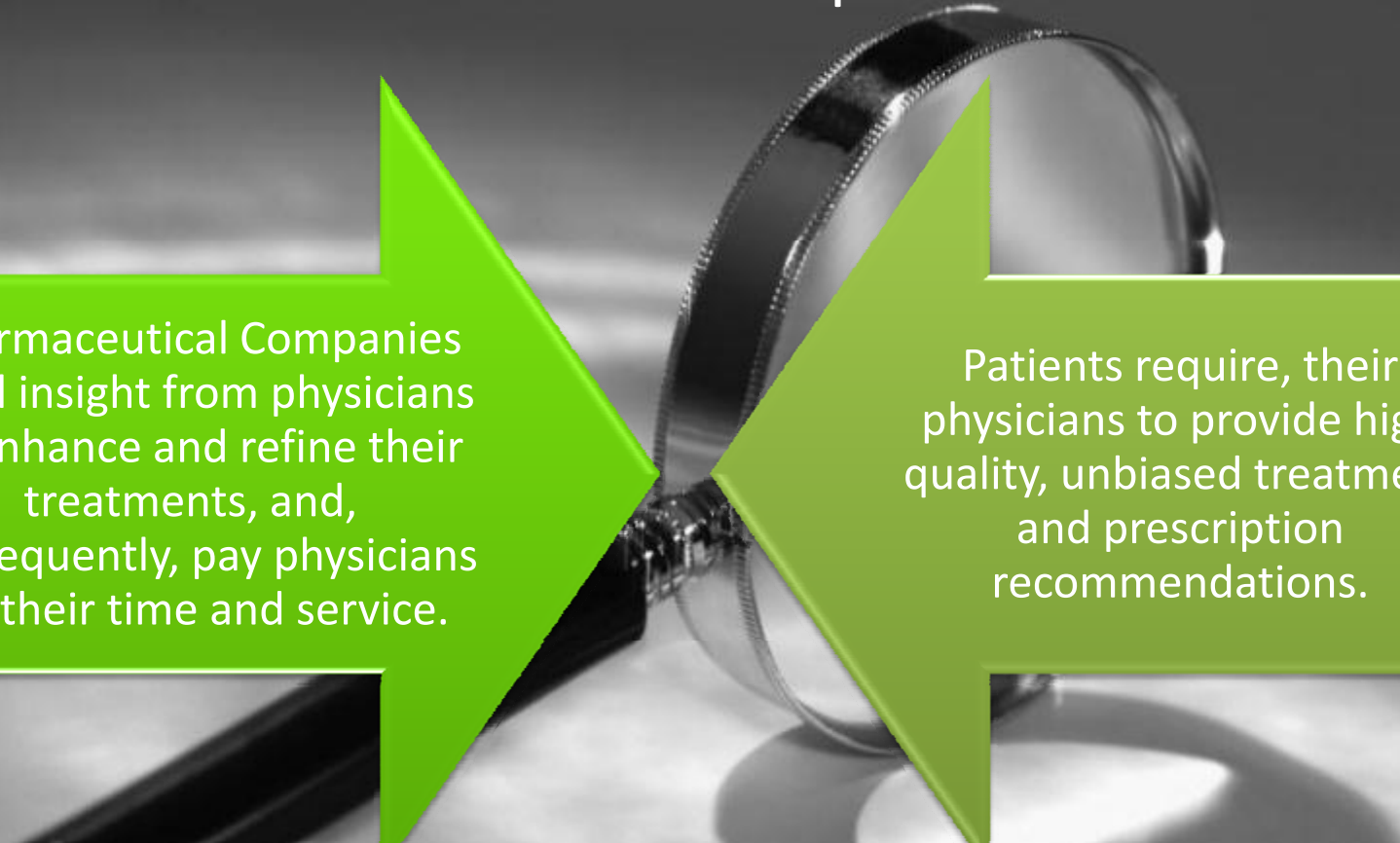
In Germany, the doctrine of "employer consent" and the German Pharmaceutical Act set light approaches



Reliable Information

It can be trusted 

Pharmaceutical Companies and HCP relationships will continue to be a controversial topic

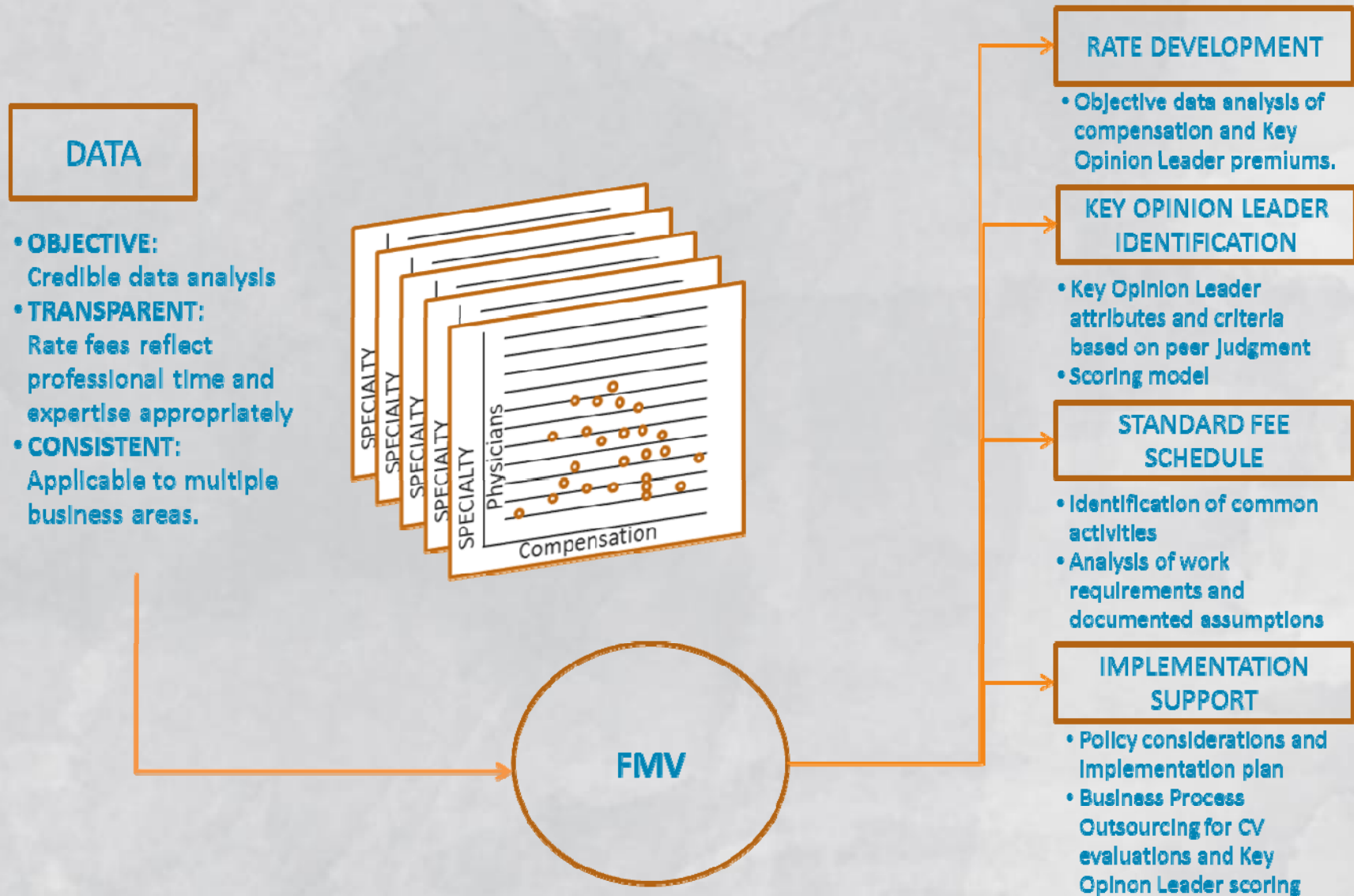


Pharmaceutical Companies need insight from physicians to enhance and refine their treatments, and, consequently, pay physicians for their time and service.

Patients require, their physicians to provide high quality, unbiased treatment and prescription recommendations.

To achieve these important goals, pharmaceutical companies must not compensate physicians at inflated levels that may bias, or appear to bias, treatment decisions. In other words, physicians must be compensated for their services to pharmaceutical firms at fair market value.

1. – Reliable information: Solid FMV Methodology



2. – Reliable information: Transfer of Value Calculation

- Companies must document and publicly disclose transfers of value made to healthcare professionals or healthcare organizations;
- Transfers of Value to be disclosed include:
 - Donations or grants;
 - Sponsorship of attendance of healthcare professionals at meetings;
 - Fees paid to healthcare professionals;
 - Contributions to the cost of meetings (including registration fees, accommodation and travel);

The disclosure of "transfers of value" in the life sciences sector

TRANSFER OF VALUE:

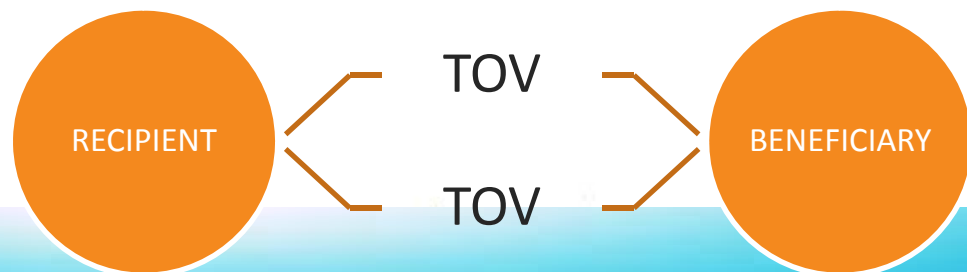
a direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines".

DIRECT:

made directly by the relevant company to the recipient of the benefit.

INDIRECT:

made by a third party on behalf of a company for the benefit of a recipient where the identity of the company is known to, or can be identified by, the recipient".



2. – Reliable information: TOV Calculation



Need to define clear business rules to provide consistent answers to the different potential TOV scenarios



Companies must provide a note summarizing their methodologies used in preparing the disclosures;

Slide 19

A1

CLARIFY SOURCE "EFPIA cODE"

Author, 4/3/2014

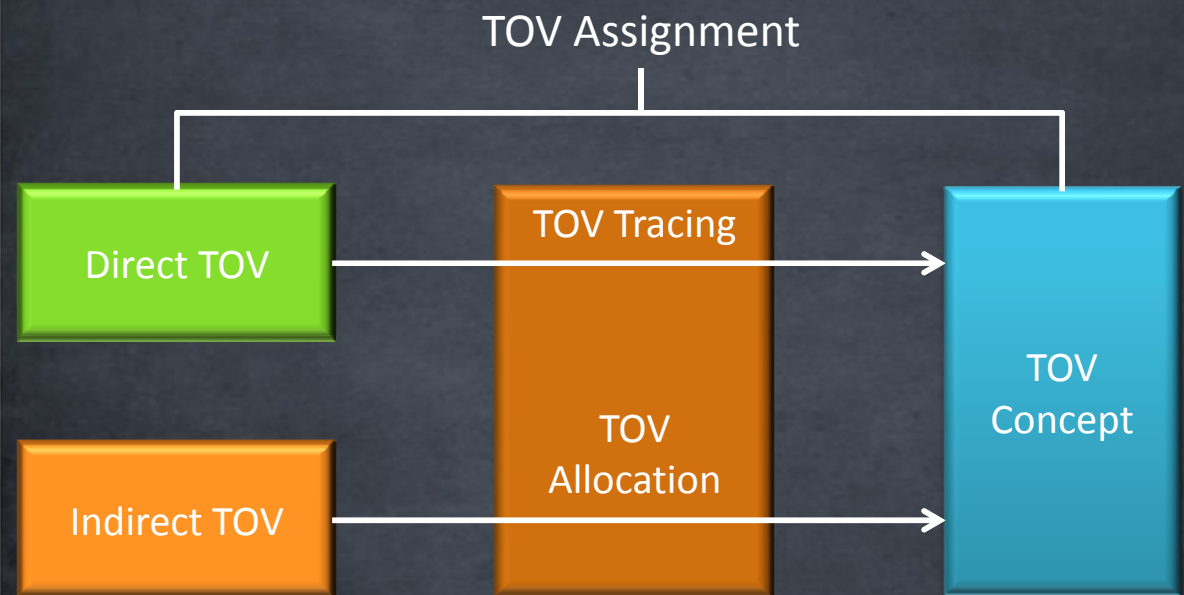
Transfer of Value (ToV) Methodology

- Clear and simple rules are required to ensure the quality and consistency of the information

“An honor system is only as good as the clarity of its rules — and the effectiveness of the oversight”²

² Nature [0028-0836] ; 2009, vol:461; 7262; 315

- It is KEY to establish clear, TRANSPARENT and consistent criteria to assign TOV.



Transfer of Value allocation process

“Direct” TOV Allocations

- Donations or Grants
- Fees paid to healthcare professionals

TOV ALLOCATIONS based on “documented” business rule

- Sponsorship of attendance of healthcare professionals at meetings;
- Contributions to the cost of meetings (including registration fees, accommodation and travel);

Key concepts to be assigned under specific business rule

- Sponsorship of attendance of healthcare professionals at meetings;
- Contributions to the cost of meetings (including registration fees, accommodation and travel);

Example of Potential TOV Scenarios and Options

Transportation – (*air fare, train, bus*):

Direct TOV assignment , with the exception of...

1. Ground Transportation:

- **Potential scenario:** In case it is offered transportation to/from Hotel and meeting venue for a group of meeting attendees
- **Potential Option:**
 - The total cost will be divided by number of days of the transport service and by all who would reasonably be expected to use the service.
 - Use individual actuals

2. Arrival/Departure Transfers:

- **Potential scenario:** One or small group of people needing transfer from their point of arrival to the event or hotel
- **Potential Option:**
 - A reasonable estimate of the cost will be allocated to the passenger(s). If there is more than one passenger the amount should be divided among them.
 - Actuals by individuals



Example of Potential TOV Scenarios and Options

Accommodation:

- a) Individual assignments:
 - easiest scenario.
- b) Collective delegate management:
 - Need to establish clear process for TOV assignment.
 - **Potential scenario:** Hotel room rate variations
 - And number of nights stay
 - **Proposed Options:** to define specific business rules:
 - *Ex.: Average rate across the booking at the time the hotel is contracted.*

TOV = Avg. negotiated room rate **X** number of nights

- *Actuals by individual ...*



Example of Potential TOV Scenarios Options

Registration Fee

- Support to HCP **Registration Fee** payment:
 - Individual → Direct Assignment
 - Group of attendees:
 - TOV assignment on negotiated rates
 - *TOV assignment for special rates (ex.: membership levels).*



OTHER – ex.: Food & Beverage

- Group of attendees:
 - Option to estimate “**daily value**” to be used for all delegates.
- **Options:**
 - TOV is made based on daily meeting attendance status.
 - Other option would be reporting actual
- Need to define “points of control” to prevent to exceeding **defined limits**



Note: *food and beverage not required for EFPIA reporting*

Other concepts to pay attention...

Co-Payments

- In some countries – In order to be in compliance with specific local codes/regulations – need to define specific rules in case of “co-payment”:
- **Potential Option:** HCP to reimburse the company a given percentage of TOV concepts (such as lodging and/or transportation)

– *Need „case by case“ adjustment to enter actual „Co-Pay“ amounts at the attendee level (In accordance to the amount invoiced to the attendee)*



Taxes

- *While EFPIA is not giving guidance.*
- *Unless there is a local legal requirement - This requires to define a “company” position to be documented in the methodology note to be disclosed.*



In Summary...

Need for open collaboration among all incumbent parties





Trust and Confidence

- HCPs and HCOs should be fairly compensated for the services they provide to collaborate with Pharma Companies to improve patient care.
- Interactions among Industry, HCP and HCOs should be transparent.
- The aim is that the information disclosed will give patients and other stakeholders a better understanding of, and ultimately build trust in the industry interactions with the medical profession



Reliability and Consistency

- Intends as the EFPIA code, proposed countries (trade associations) and companies to embrace consistent levels of transparency in all markets. However, individual country laws related to industry transparency need to be considered individually.



Partnership and Collaboration

- It is important the collaboration among Pharma, HCPs and HCOs.
- Trust and Transparency require all the parties to work in the same principles, to provide visibility and understanding to assure to the society on our commitment to ethical behaviour.

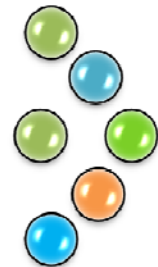
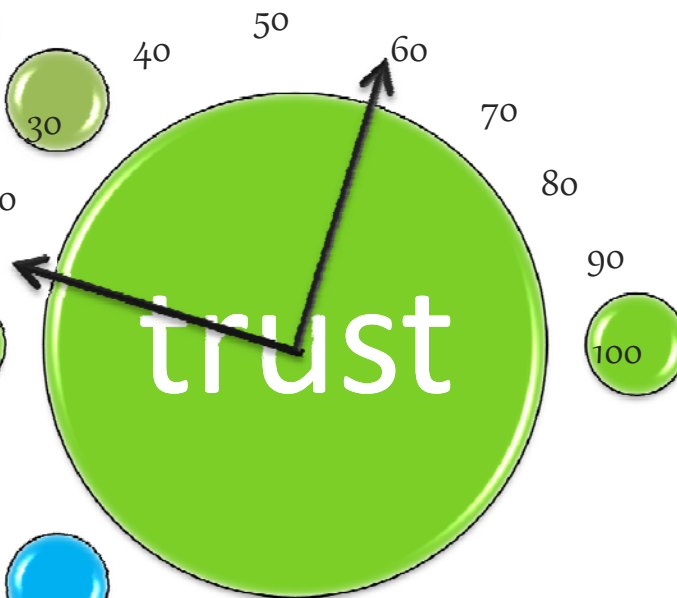
Transparency



Reliable
information



Legitimate need



4th Annual



Global Transparency Reporting Congress

Determine the True Financial Value of a Transaction

José Ramos, MD
Transformation Manager
Lilly S.A. (Spain)