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The value of Transparency in the life science sector

London, Sept 26th, 2013



The task

January 2013, the Strategic Committee defined three work streams. Work stream 1 was to:

“create an expert sounding board forum to debate and discuss the value of Transparency in our sector (...).”

The “call to arms”

March 7th, 2013 email calling in for participation:

“We believe that this project is very important in three ways:

- It will help us to better understand the various approaches to and understanding of what transparency in the healthcare sector actually mean to the diverse stakeholders in our field.
- As a result, we will be able to better understand what the stakeholders’ expectations are and
- how these expectations align (or don’t) with our expectations as compliance professionals and with the expectations of the companies we work for, i.e. what the actual value proposition for transparency is.

The team

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The developments

- décret May 21, 2013 to the Loi Bertrand
- June 24, 2013: efpia code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations with very specific requirements and an implementation deadline by December 31, 2013.

Our reaction

- our realisation that to bring together experts to determine the varying stakeholders' views on transparency would be very difficult in a context where many significant developments have already taken place.
- A quick reference guide to transparency rules in the 27 most relevant markets among the EU/EFTA countries (as of July 2013).
- Re-evaluate the benefits of an expert sounding board on the value of transparency.

The reference guide

- Listing of existing transparency rules in 27 of the most significant markets among EU/EFTA countries (as of July/August 2013).
- brief overview of what is to be disclosed to whom, when and how frequently, in an aggregate or individualized mode, and on the basis of what specific part of the set of rules.

Reference guide

Transparency Tracker by Country - draft 130910.xlsx - Microsoft Excel

Start Einfügen Seitenlayout Formeln Daten Überprüfen Ansicht Acrobat

Einfügen Zwischenablage Schriftart Ausrichtung Zahl Bedingte Formatierung Als Tabelle formatieren Zellenformatvorlagen Zellen Bearbeiten

A5 Type of transparency

A	B	C	D	E	F	G	H	I	J	K	
Type of transparency	applicable to	requested by	basis for	frequency	type of reporting	GEHC	effective by	Status	reporting dates	report to	
Sunshine act = disclosure to the public	Pharma or Devices		transparency			to report					
Disclosure to authorities											
Disclosure to industry association											
5 Visa											
5	Visa	P & D	law	National Organization of Medicines we are member of	as needed	for each event and transaction	yes	Regulation is in place since many years. Latest amendment in force since 1.2.2013	effective	Reporting should take place both before the event and after.	National Organization of Medicines Regulatory body linked to MoH
6	Disclosure to industry association	P	Code of Conduct	Hellenic association of medical companies	Annually	Consolidated	yes	Obligation enforced since 1.2.2013.	effective	will be communicated by the Business association	Hellenic association of medical companies' website

Austria Belgium Croatia Czech Republic Denmark France Finland Germany Greece

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Some elements of discussion

- Transparency is still a topic, in particular in the framework of the disclosure of CT data:
 - Sept. 16th, 2004 statement from the International Committee of Medical Journal Editors (Lancet, New England Journal of Medicine,...)
 - August 2012: WHO launches the International Clinical Trial Registry Platform
 - July 24th, 2013 EFPIA-PhRMA Joint Principles for Responsible Clinical Trial Data
 - Sept. 5th, 2013 efpia response to EMA consultation on the Publication and Access to Clinical Trial Data

Some elements of discussion (ct'ed)

- trust is clearly still an issue for the healthcare industry:
 - 2012 Edelman Trust Barometer: 7th out of 11th with the brewing & spirit industry 6th
 - NEJM (Sept. 20th, 2012) article on study that showed that participating “physicians were half as willing to prescribe drugs studied in industry-funded trials as they were to prescribe drugs studied in NIH-funded trials”
- Transparency doesn't seem to be sufficient to gain trust; ranks 7th out of 16 factors to build future trust (2012 Edelman Trust Barometer)

Some suggestions & challenges

- Determine what the factors could be for the healthcare industry to regain trust
- What the role of compliance officers in companies could/should be in this context:
 - Managing the process of disclosure?
 - Managing the processes of the activities to be disclosed?
- However some challenges will remain:
 - Which experts to invite?
 - Under what format (face-to-face meetings, resources)?
 - what outcome (white paper, ..?)

**Your thoughts,
recommendations and wishes
as to
the direction to take and
next steps**