

Global Transparency Update

Advanced Issues in Transparency and Disclosure

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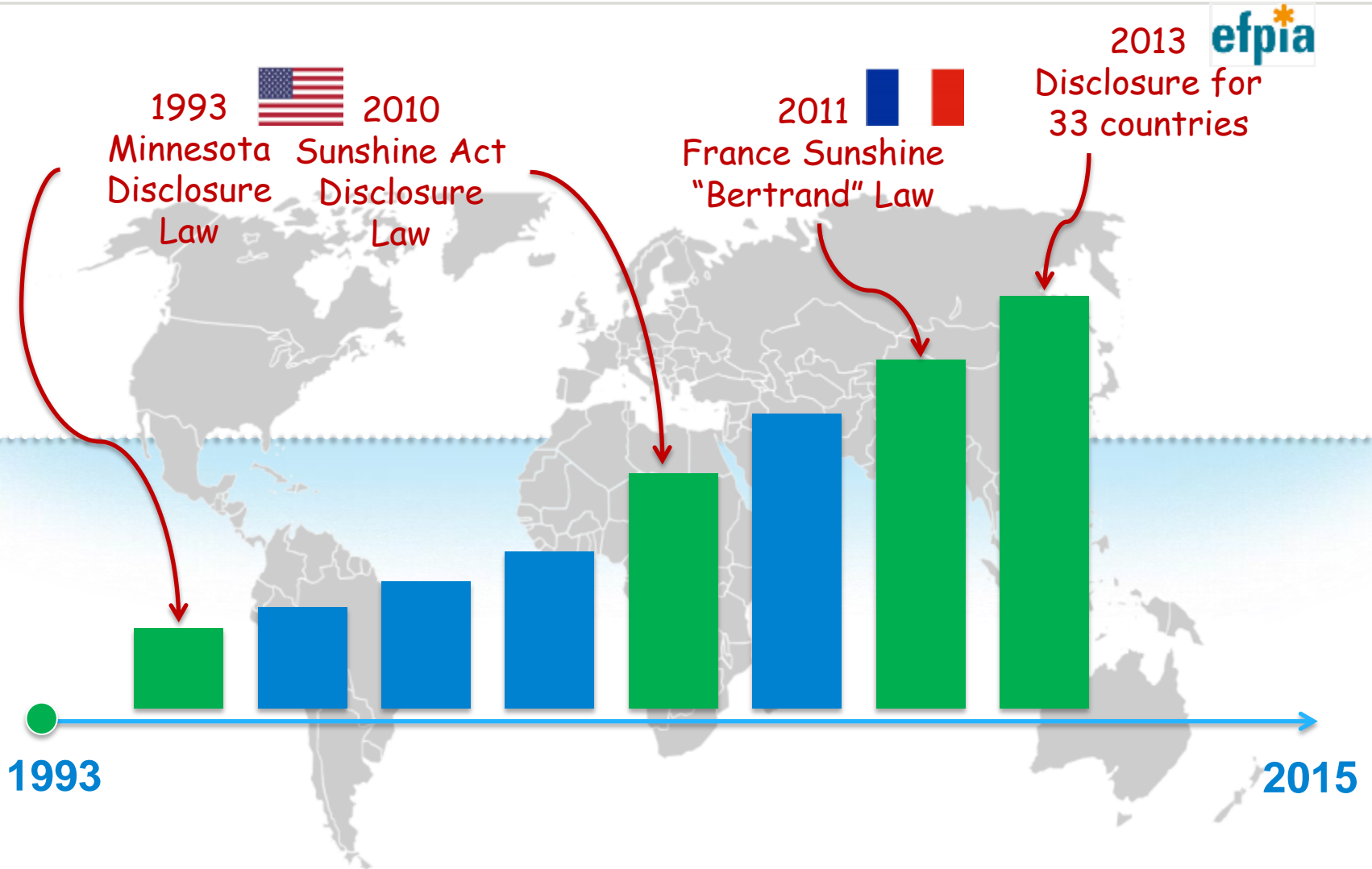


The Need for Transparency Reporting
















To comply with

- US States Laws
- US Federal Law
- National Laws
- Regional Codes of Disclosure
- National Transpositions of Regional Codes of Disclosure
- Internal Transparency monitoring initiatives

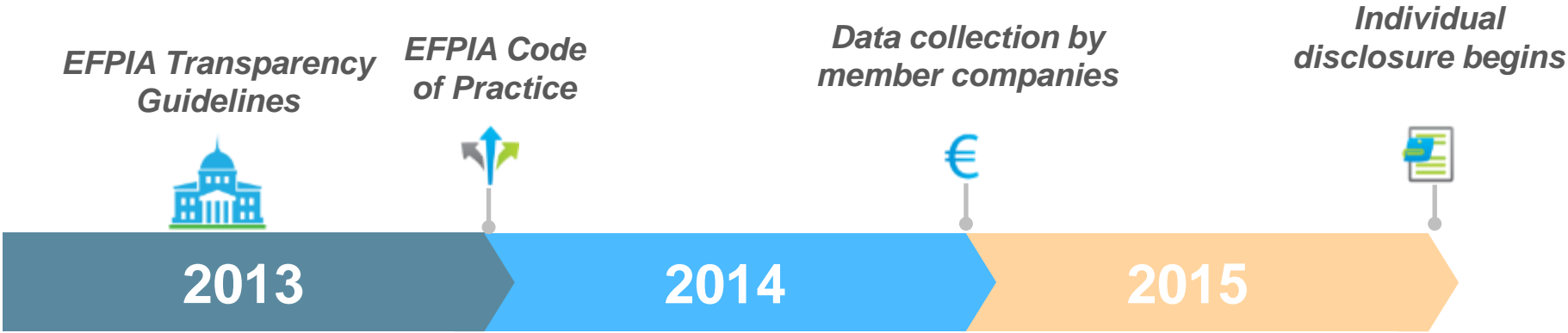
Evolution of the need



Global Landscape for Disclosure Reporting

U.S. Federal Law			Code	33 countries
U.S. State Laws (Washington, D.C., Massachusetts, Minnesota, Vermont, etc.)		Denmark	Law	
	Fees and Expenses for Service and Consultancy	France	Law	
	Donations and Grants	Portugal	Law	
	Contribution to costs related to events: <ul style="list-style-type: none">• Registration fees• Sponsorship agreements• Travel and accommodation	Slovakia	Law	
	Research and Development	Netherlands	Code	
	Individual and Aggregate Data	United Kingdom	Code	
		Australia	Code	
		Japan	Code	

European Transparency (EFPIA) Timing



Aggregate R&D



Individual HCO



Individual HCP



Disclosure in **June 2016** based on **2015 data**

EFPIA Template for Reporting

Based on consent status

Annex 2 - TEMPLATE - DISCLOSURE OF TRANSFERS OF VALUE												
Art. 44ter.3											Date of publication:	
Full Name <i>(Art. 44bis)</i>	HCPs: City and zip code of Principal Practice HCOs: City and zip code of Headquarters <i>(Art. 44quater)</i>	Country of Principal Practice <i>(Art. 44bis.2)</i>	Principal Practice / Headquarters Address (street/n°/post. box) <i>(Art. 44quater)</i>	Unique country local identifier OPTIONAL <i>(Art. 44quater)</i>	Donations and Grants <i>(Art. 44quater.2.1.a)</i>	Contribution to costs of scientific events <i>(Art. 44quater.2.1.b & 44quater.2.1.a)</i>			Fee for service and consultancy <i>(Art. 44quater.2.1.c & 44quater.2.1.b)</i>			TOTAL OPTIONAL
						Sponsorship agreements with HCOs / third parties appointed by HCO's to manage a scientific event	Registration Fees	Travel & Accomodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel & accomodation relevant to the contract		
INDIVIDUAL NAMED DISCLOSURE - one line per HCP (i.e. all transfers of value during a year for an individual HCP will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, upon request)												
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												
Aggregate amount					N/A	N/A	Aggregate amount	Aggregate amount	Aggregate amount	Aggregate amount		Optional
Number of Recipients (named list, where appropriate) - Art. 44quater.3					N/A	N/A	number	number	number	number		Optional
% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art. 44quater.3					N/A	N/A	%	%	%	%		N/A
INDIVIDUAL NAMED DISCLOSURE - one line per HCO (i.e. all transfers of value during a year for an individual HCO will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, upon request)												
HCO 1					Yearly amount	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	Yearly amount	Optional
etc.					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Optional
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. 44quater.3					Aggregate amount	Aggregate amount	Aggregate amount	Aggregate amount	Aggregate amount	Aggregate amount	Aggregate amount	Optional
Number of Recipients (named list, where appropriate) - Art. 44quater.3					number	number	number	number	number	number	number	Optional
% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art. 44quater.3					%	%	%	%	%	%	%	N/A
AGGREGATE DISCLOSURE												
Transfers of Value re Research & Development as defined in art. 44quater.5											TOTAL AMOUNT	OPTIONAL

Consent Management

Key Points

- When making a Transfer of Value (ToV) to a HCP/HCO, companies are encouraged to include provisions relating to the recipients' consent to disclose ToV.
- Companies should make their best efforts to obtain the consents necessary to disclose ToV individually and in aggregate in exceptional circumstances only.
- If a significant number of recipients refuse to consent to public disclosure for the ToVs they receive, companies will then report mainly at the aggregate instead of the individual level.
- Aggregate reporting will not likely to be sufficient to convince governments and legislators to refrain from regulating.

Operational Approach

Six Elements to consider when complying with Requirements

1. Diverse Legal Environment
2. Diverse IS Landscape
3. Unique Identifier
4. Relationship with Recipients
5. Global vs. Local Baseline
6. Traceability and Documentation

I. Transparency Requirements Update

The following countries are undergoing legislative, regulatory or industry code changes, so the situation may not be completely final:

1. **Colombia** - no law for now, but lobbying political pressure
2. **Denmark** – HCPs have to manually fill-in govt website
3. **Latvia** – awaiting legislative initiative
4. **Lithuania** – awaiting legislative initiative in May 2015
5. **Portugal** – national law is final, but code transposition from Apifarma does not include technical specifications
6. **Romania** – March 2015 law on TOV disclosure; technical specifications pending
7. **Slovakia** – implications of 2015 Income Tax law pending

Thank You !!!