

Advanced Issues in Global Transparency, Disclosure and Aggregate Spend Compliance

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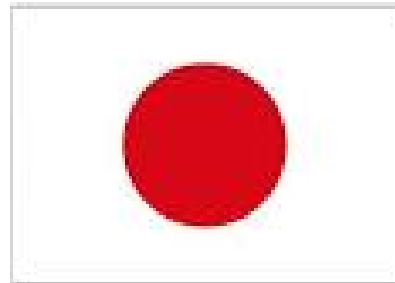
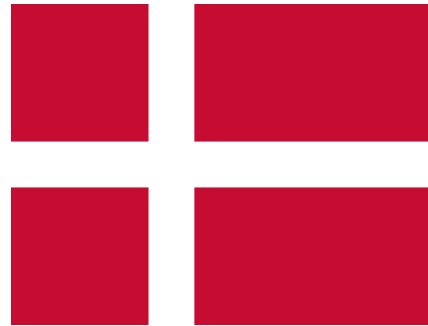
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The Ninth International Pharmaceutical Compliance Congress and
Best Practices Forum

Brussels, Belgium

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A map of Europe with the word 'efpia' in large blue lowercase letters. An orange asterisk is positioned above the 'i'. The map shows the outlines of European countries in light beige against a blue background representing the sea.

efpia*

Austria

Belgium

Bulgaria

Croatia

Cyprus

Czech Republic

Denmark

Estonia

Finland

France

Germany

Greece

Hungary

Norway

Poland

Portugal

Romania

Russia

Serbia

Slovakia

Slovenia

Spain

Sweden

Switzerland

Turkey

Ukraine

United Kingdom

Ireland

Italy

Latvia

Lithuania

Malta

Netherlands

Transposition

EFPIA Disclosure Form:

- Central platform developed by association (Belgium, Czech Republic, Greece, Sweden, UK);
- Governmental platform (The Netherlands, Denmark, France, Portugal)
- Company websites (Austria, Croatia, Estonia, Finland, Germany, Hungary, Ireland, Italy, Latvia, Malta, Slovenia, Spain, Switzerland, Turkey);
- National association websites linking to company websites (Bulgaria, Cyprus, Lithuania, Norway, Poland, Romania, Ukraine);
- Optional: companies may choose to disclose on a central platform or on their company website (Russia, Serbia, Slovakia).

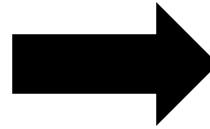
SCHEDULE 2 - TEMPLATE													Date of publication: _____	
Full Name (JAN 2.02)	HCF: City of Principal Practice HCOs: city where registered (JAN 2)	Country of Principal Practice (JAN 3)	Principal Practice Address (JAN 5)	Union country member OPTIONAL (JAN 6)	Description and Grant MFCs (JAN 7.1 & 7.2)	Contribution to costs of Events (JAN 8.01, 8.2 & 8.01, 8.2)			Fees for services and consultancy (JAN 8.01, 8.2 & 8.01, 8.2)			Related expenses agreed in the fee for services or consultancy contract, including administration expenses in the contract	TOTAL OPTIONAL	
						Nonmarketing agreements with HCFs that parties approved by HCOs in exchange for Events	Registration Fees	Taxid & Accommodation	Fees	Travel	Consultancy			
INDIVIDUAL NAMED DISCLOSURE - see line per HCF J2, all transfers of value during a year for an individual HCF will be reported as transfers should be reported by the individual recipient or their authorized representative only, as appropriate														
J2.1								Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Optional
J2.2								Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Optional
J2.3								Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Optional
OTHER, NOT INCLUDED ABOVE - unless information cannot be disclosed on an individual basis for legal reasons														
J2.4								Aggregate HCFs	Aggregate HCFs	Aggregate HCFs	Aggregate HCFs	Aggregate HCFs	Aggregate HCFs	Optional
J2.5								Number of Recipients to aggregate disclosure - Art 3.02	Number of Recipients to aggregate disclosure - Art 3.02	Number of Recipients to aggregate disclosure - Art 3.02	Number of Recipients to aggregate disclosure - Art 3.02	Number of Recipients to aggregate disclosure - Art 3.02	Number of Recipients to aggregate disclosure - Art 3.02	Optional
J2.6								% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art 3.02	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art 3.02	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art 3.02	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art 3.02	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art 3.02	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art 3.02	Optional
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J3.6								% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art 3.02	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art 3.02	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art 3.02	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art 3.02	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art 3.02	% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art 3.02	Optional
AGGREGATE DISCLOSURE														
J4.0	Transfers of Value in Research & Development as defined - Article 3.04 and Schedule 1											TOTAL AMOUNT	OPTIONAL	

last update: 17 December 2013 41

Consent

- ▶ “When making a transfer of value to a healthcare professional/healthcare organisation, and in their written contracts, companies are encouraged to include provisions relating the recipient’s consent to disclose transfers of value in accordance with the provisions of the EFPIA HCP/HCO Disclosure Code.”

DIRECTIVE 95/46/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 24 October 1995
on the protection of individuals with regard to the processing of personal data and on the free
movement of such data

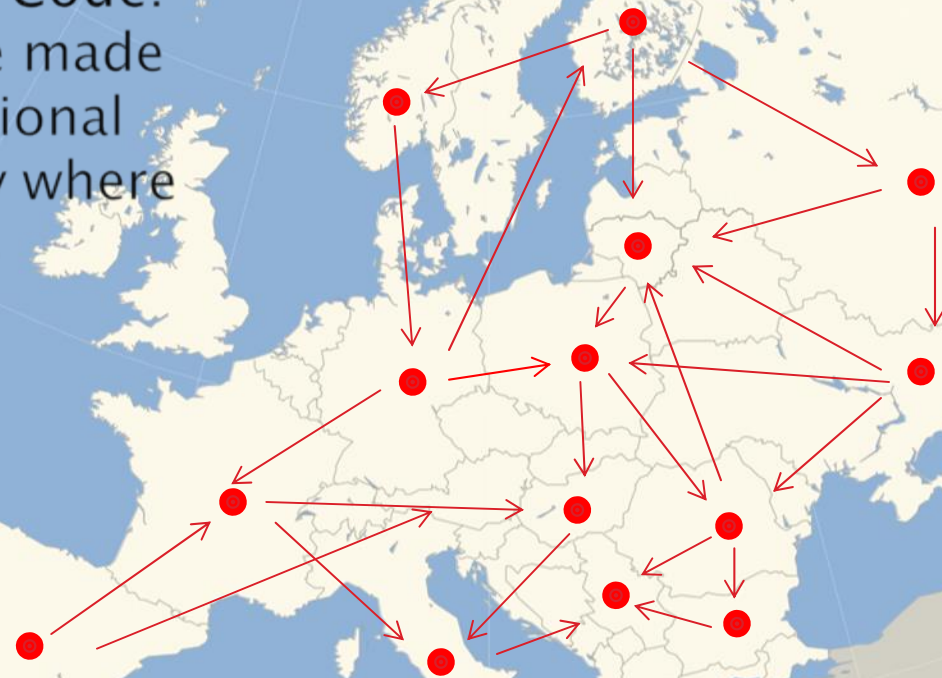


HCP Interaction



Cross Border

Applicable National Code:
Disclosures shall be made
pursuant to the National
Code of the country where
the recipient has its
physical address

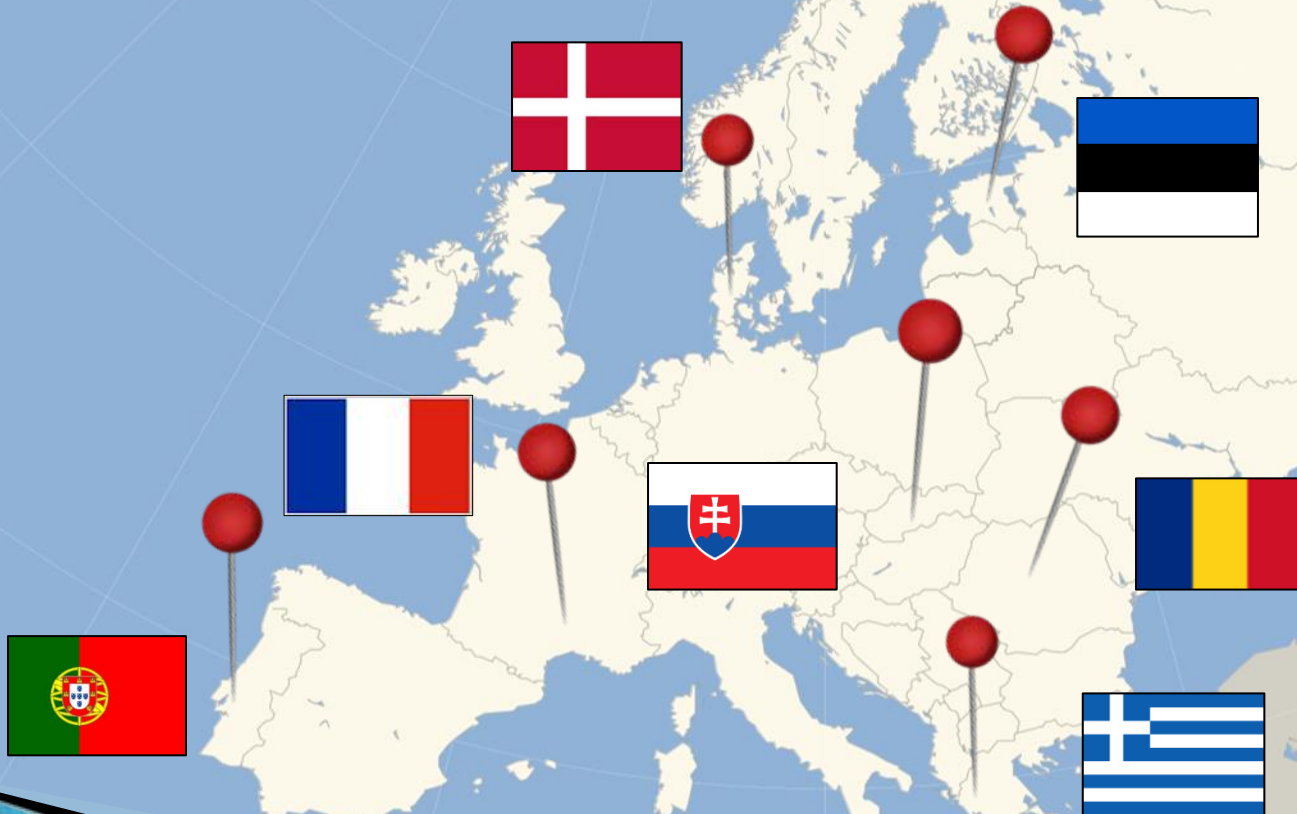


Methodology

- ▶ **Methodology** – Companies shall publish a note summarizing the methodologies used in preparing their disclosures and identifying transfer of value to each category. This note may include information on contracts, tax aspects, currency aspects or other issues related to the timing or amount of the transfer of value.



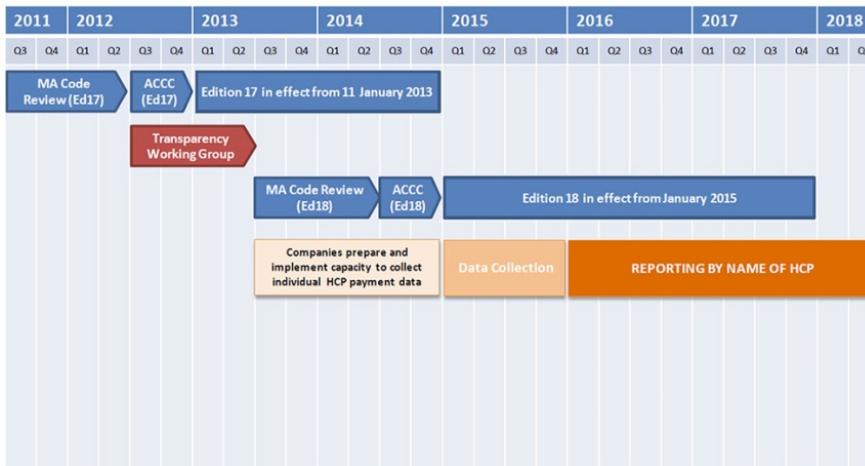
Laws



Other Hot Spots



TIMELINE CODE OF CONDUCT TRANSITION TO GREATER TRANSPARENCY



"Transparency Guideline for the Relation between Corporate Activities and Medical Institutions"

The Japan Pharmaceutical Manufacturers Association

Established: January 19, 2011
Revised: March 21, 2013

The purpose of this Guideline is to gain wide understanding of the pharmaceutical industry's contribution to life science such as medicine and pharmacy, and that corporate activities are conducted with high ethical standards, by making the relation between member company's activities and medical institutions, etc. transparent.

- Each member company shall prepare its own in-house "Policy for Transparency" as a code of practice, referring to this Guideline.
On preparing the in-house "Policy for Transparency", the following preparatory arrangements should be made with the premise that the payments made in fiscal 2012 are disclosed in fiscal 2013.
 - Establishment of procedures to obtain agreement from medical institutions, etc. on information disclosure (procedures for making consignment contracts on the premise of information disclosure)
 - Early establishment of systems needed for aggregation and disclosure of payments, etc.
- It is desirable for the following items to be included in the in-house "Policy for Transparency".
 - Each member company's stance**
To express member company's corporate policy for transparency of relation with medical institutions, etc., and that all activities performed by the member company follow the rules specified by the Japan Pharmaceutical Manufacturers Association (hereinafter referred to as "JPMA") such as "JPMA Corporate Activity Charter", "JPMA Compliance Program Guideline", "JPMA Code of Practice" and other regulations concerned and the spirit intended therein.
 - Disclosure method**
Each member company shall disclose the payments in the previous fiscal year through each company's website after financial closing.
 - Timing of disclosure**
The payments in fiscal 2012 shall be disclosed from fiscal 2013.
However, the disclosure of number of services and amount of payment in "C. Manuscript/writing fees, etc." included in "(4) Targets of disclosure" will be disclosed from fiscal 2014 for 2013 data.
 - Targets of disclosure**
 - Research and development expenses



U.S. Experience



Other Challenges



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