Do Start Believin'

PORZIO LifeSciences

Brian P. Sharkey

The Global Transparency Journey for the Life Sciences Industry Webinar

October 2, 2014

Born in the USA

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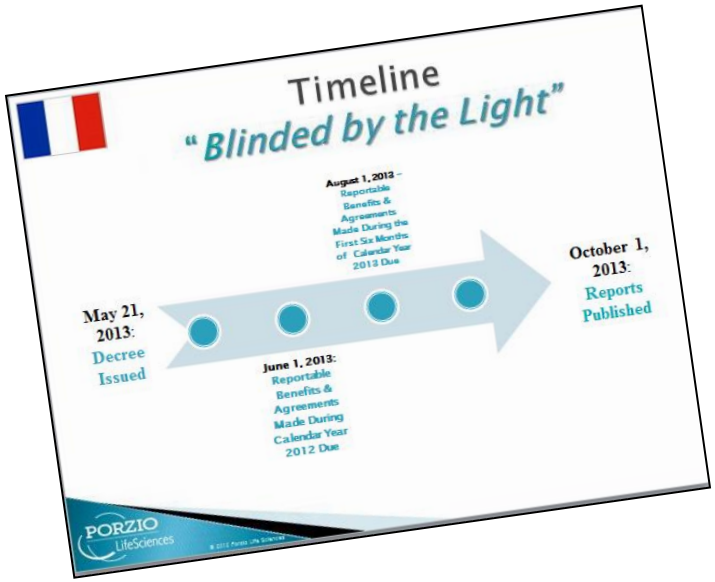

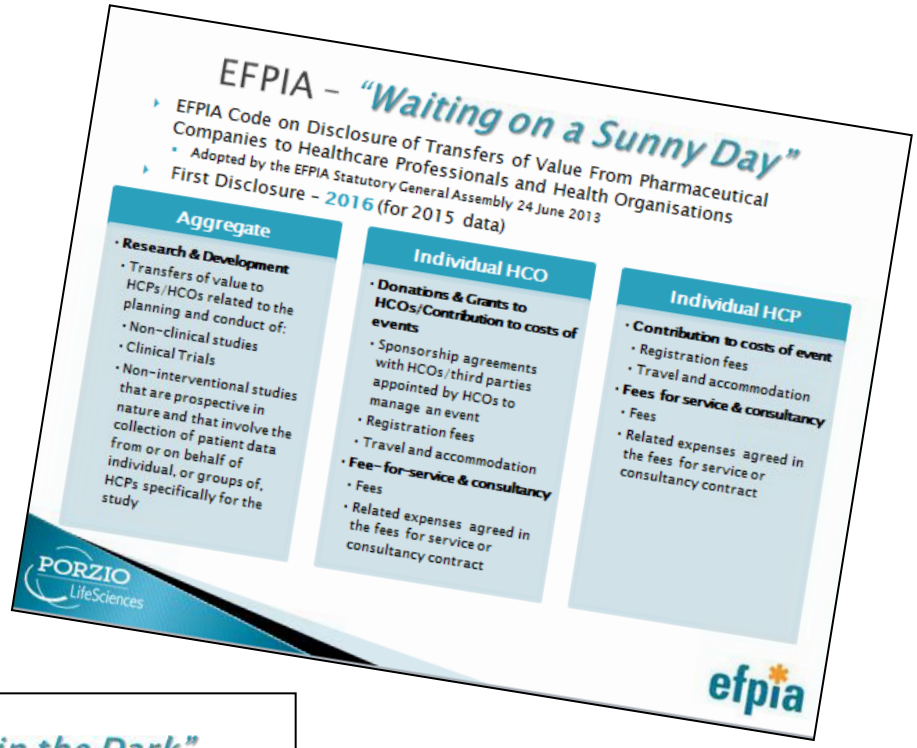

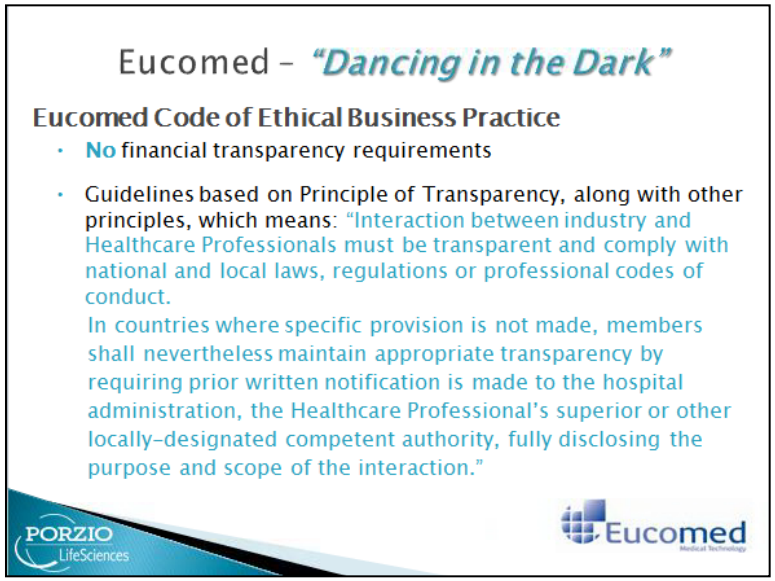

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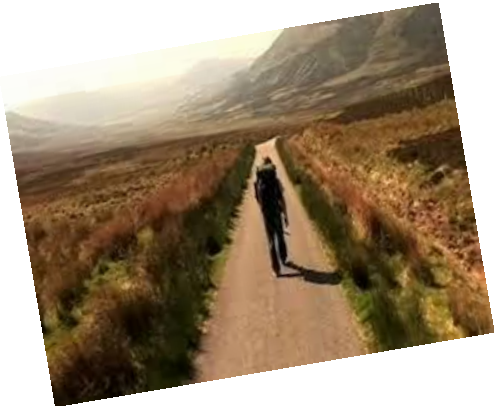

Journey

A Journey Inspired by Journey

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Themes

Pharmaceutical Industry
v.
Medical Device Industry

Eucomed
Medical Technology

Laws v. Codes

IFPMA

efpia

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LifeSciences

European Union

- European Union Directives or Regulations
  - No Disclosure/Reporting Requirements

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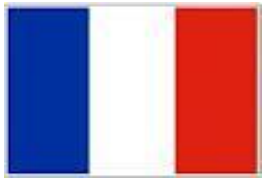

France "Sunshine" Law

Passed in December 2011

Requires:

Companies to disclose to public all agreements they have with, and certain benefits given to, specified recipients.

Violations:

- Criminal sanctions: € 45 000 fine in case of deliberate omission of disclosure for an individual (€ 225 000 for a company)
- Other sanctions: posting of sanctions, prohibition to manufacture products, civil rights suspension

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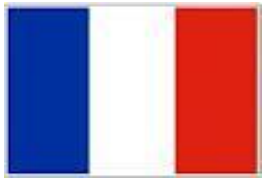
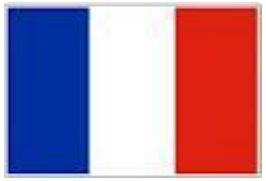


Covered Recipients

The final decree imposes two main types of disclosure requirements on pharmaceutical and medical device companies: Companies must disclose the existence of agreements with and benefits provided to the following:

1. Healthcare professionals (e.g., physicians, nurses, but the disclosure requirements do not apply to the reporting company's employees);
2. Associations of healthcare professionals and associations of students for relevant occupations;
3. Students for relevant occupations;
4. User associations of the health system (public or private);
5. Health facilities;
6. Foundations, learned societies, and consulting companies or organisations in the health sector;
7. Publishing companies: press, radio, television, and on-line media;
8. Editors of prescription and dispensing software; and
9. Legal entities contributing to the initial training of healthcare professionals.



Agreements with Recipients

For **agreements**, companies must reveal the following:

1. the identity of the parties to the agreement:
   a. For healthcare professionals: name, professional address, qualifications, title, specialty, and registration number with the relevant professional board;
   b. For healthcare students: name and educational institution;
   c. For legal entities, like associations, health institutions, etc.: name, corporate purpose, and registered address;
2. the date the agreement was signed;
3. the subject matter of the agreement (which can be phrased in such a way as to protect confidential and trade secret information);
4. Program of promotional/scientific events, if applicable.

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Disclosing Benefits

Companies must disclose all **benefits** that they provide:

- whether direct or indirect, in kind or in cash, to the aforementioned recipients if the **benefits are equal to or exceed ten Euros**, inclusive of VAT.
- Benefits worth **less than ten Euros** do not have to be disclosed.
- In disclosing benefits, companies must identify the recipient and the recipient's personal information in the same manner as for agreements (e.g., name, address, title), the amount of each benefit the date and nature of each benefit and the **time period** (either the first six months of a year or the latter six months) during which the benefit was received.

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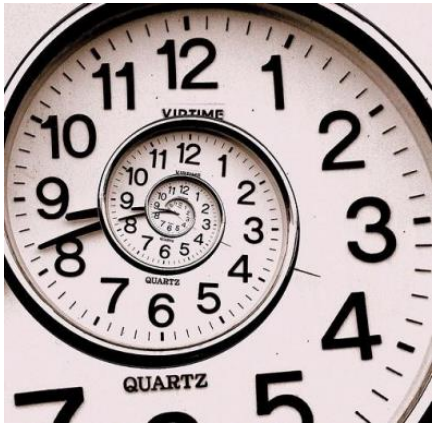
Timing

- **Agreements:** Companies must report the pertinent information for agreements to the public authority within **fifteen days** of the signing of the agreement.

- There is a pending, proposed decree that would eliminate the 15-day requirement and require agreements to be reported on the same schedule as benefits.

- **Benefits:** Relevant information for **benefits** must be reported bi-annually: by August 1 for benefits provided from January to June of a calendar year, and by February 1 for benefits provided from July through December of the preceding calendar year.



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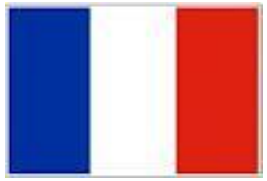


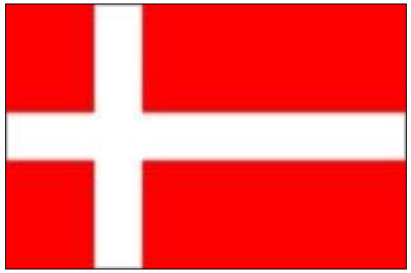
Governmental Website For French Reporting

- In a 3 December 2013 decree, which became effective on December 19, the French government established the public website and charged the French Ministry of Health with the responsibility for operating it.

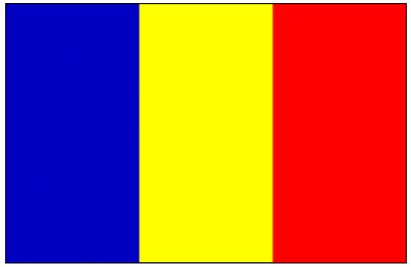
- The decree included additional provisions concerning how companies can register on the website; how data is to be transmitted to the website; and how individuals who have information reported about them can request correction of the information.

- The decree reiterated that the reported information must remain available on the website for five years and that the French Ministry of Health must retain the data for ten years. The information on the website was made available to the public in 2014.

Additional Countries



Denmark



Romania

Portugal

Slovakia

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IFPMA

- International Federation of Pharmaceutical Manufacturers & associations Code of Pharmaceutical Practices ("IFPMA Code")
  - No Disclosure/Reporting Requirements

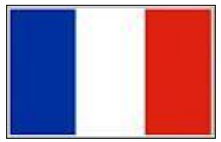
EFPIA Full Members


Austria


Belgium


Denmark


Finland


France


Germany


Greece


Ireland

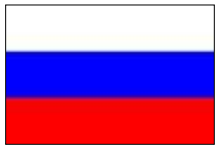

Italy


Netherlands


Norway


Poland


Portugal


Russia


Spain


Sweden


Switzerland


Turkey


United Kingdom

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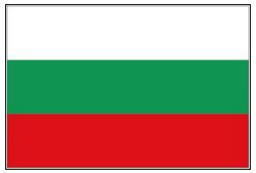
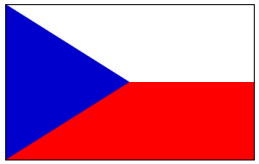
EFPIA Affiliate Members



Bulgaria

Croatia

Cyprus



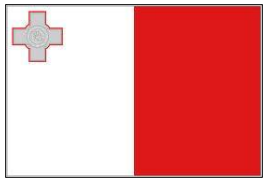
Czech Republic

Estonia

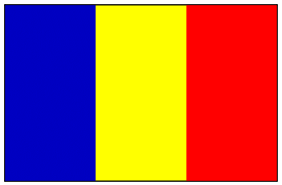
Hungary

Latvia

Lithuania



Malta



Romania

Serbia

Slovakia

Slovenia

Ukraine

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EFPIA Member Companies

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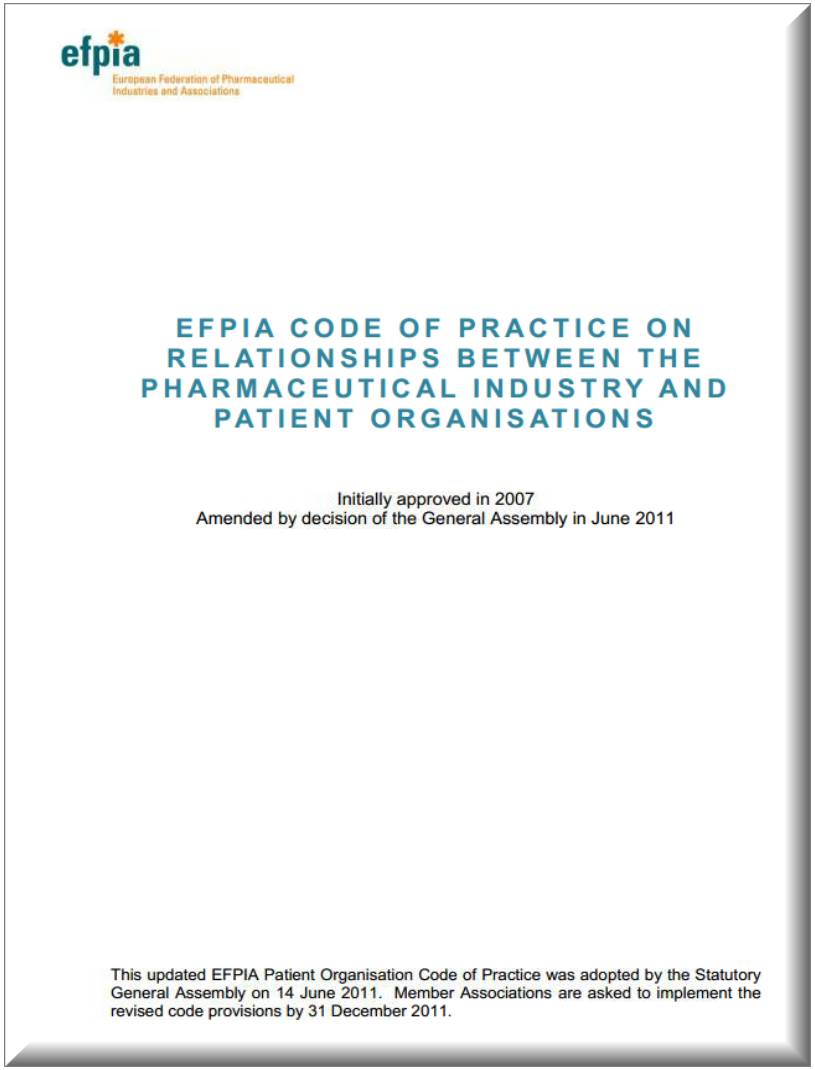
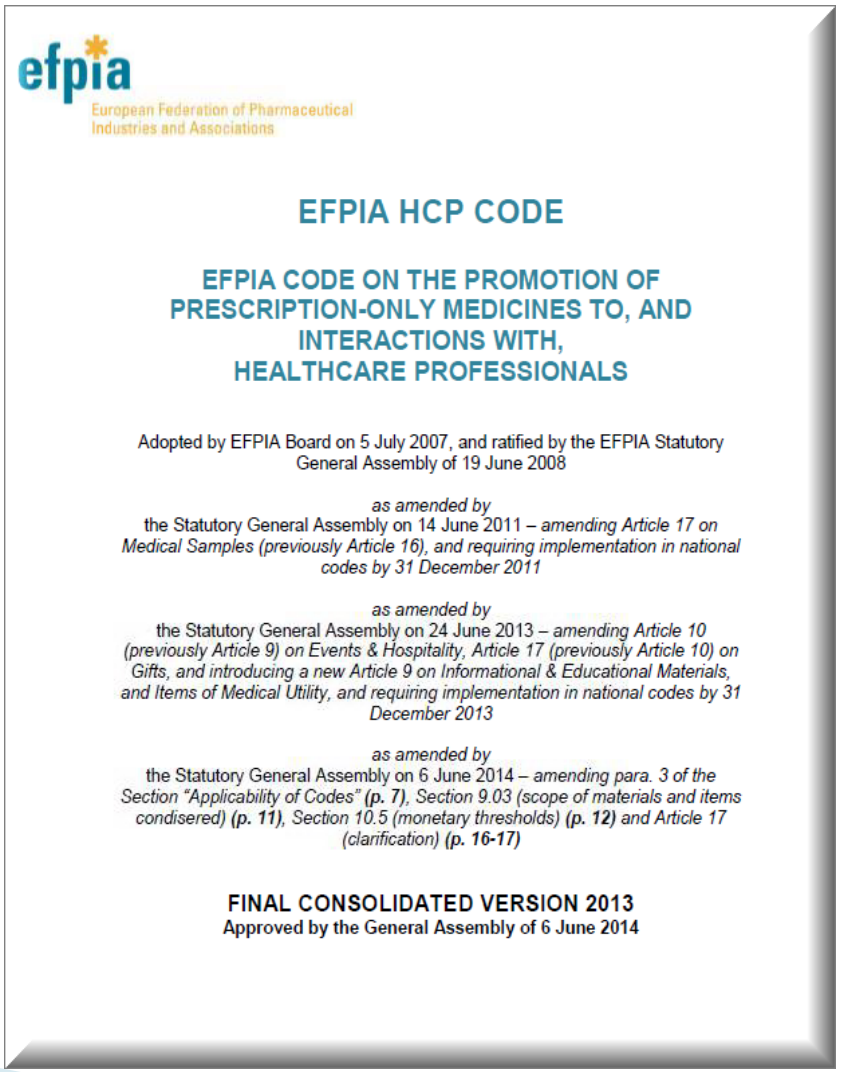


efpia
European Federation of Pharmaceutical Industries and Associations

EFPIA CODE OF PRACTICE ON RELATIONSHIPS BETWEEN THE PHARMACEUTICAL INDUSTRY AND PATIENT ORGANISATIONS

Initially approved in 2007
Amended by decision of the General Assembly in June 2011

This updated EFPIA Patient Organisation Code of Practice was adopted by the Statutory General Assembly on 14 June 2011. Member Associations are asked to implement the revised code provisions by 31 December 2011.



efpia
European Federation of Pharmaceutical Industries and Associations

EFPIA HCP CODE

EFPIA CODE ON THE PROMOTION OF PRESCRIPTION-ONLY MEDICINES TO, AND INTERACTIONS WITH, HEALTHCARE PROFESSIONALS

Adopted by EFPIA Board on 5 July 2007, and ratified by the EFPIA Statutory General Assembly of 19 June 2008

as amended by
the Statutory General Assembly on 14 June 2011 – *amending Article 17 on Medical Samples (previously Article 16), and requiring implementation in national codes by 31 December 2011*

as amended by
the Statutory General Assembly on 24 June 2013 – *amending Article 10 (previously Article 9) on Events & Hospitality, Article 17 (previously Article 10) on Gifts, and introducing a new Article 9 on Informational & Educational Materials, and Items of Medical Utility, and requiring implementation in national codes by 31 December 2013*

as amended by
the Statutory General Assembly on 6 June 2014 – *amending para. 3 of the Section "Applicability of Codes" **(p. 7)**, Section 9.03 (scope of materials and items condisered) **(p. 11)**, Section 10.5 (monetary thresholds) **(p. 12)** and Article 17 (clarification) **(p. 16-17)***

FINAL CONSOLIDATED VERSION 2013
Approved by the General Assembly of 6 June 2014

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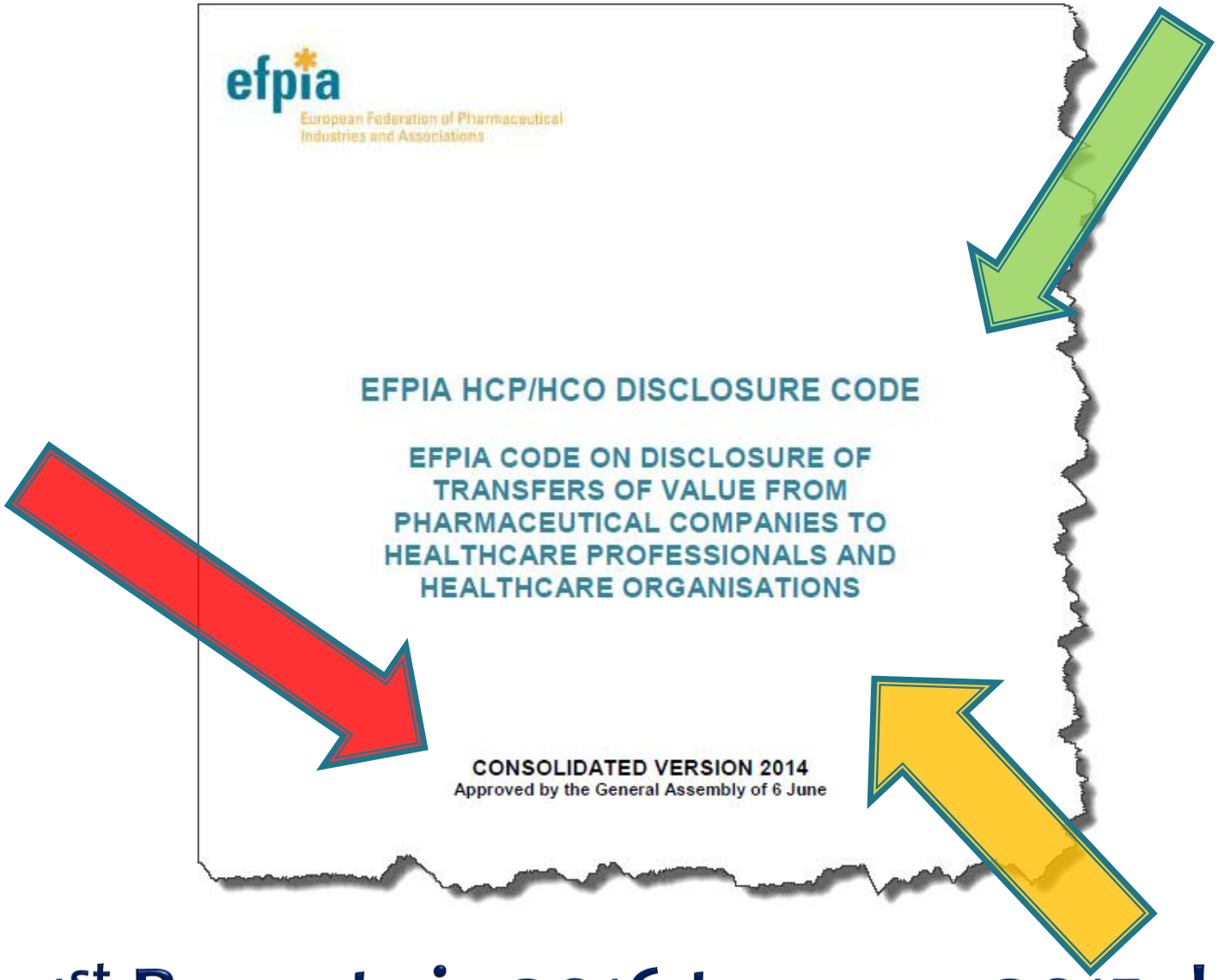

1st Reports in 2016 to cover 2015 data

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TOV Provisions: Individual HCO

A. **Donations & Grants to HCOs**
B. **Contribution to costs of events**
   i. Sponsorship agreements with HCOs/third parties appointed by HCOs to manage an event
   ii. Registration fees
   iii. Travel and accommodation
C. **Fee-for-service & consultancy**
   i. Fees
   ii. Related expenses agreed in the fees for service or consultancy contract

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TOV Provisions: Individual HCP

A. **Contribution to costs of event**
   i. Registration fees
   ii. Travel and accommodation
B. **Fees for service & consultancy**
   i. Fees
   ii. Related expenses agreed in the fees for service or consultancy contract

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TOV Provisions: Aggregate

A. Research & Development

i. Transfers of value to HCPs/HCOs related to the planning and conduct of:

a) Non-clinical studies

b) Clinical Trials

c) Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study

ii. When a company cannot report at the individual level for a HCP/HCO, e.g., lack of consent, the company must report in the aggregate.

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EFPIA Principles

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.

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EFPIA Principles

Language – Disclosures must be made in the language prescribed in the national code by the relevant member association. However, companies are encouraged to make disclosures in English in addition to the local language.

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EFPIA Principles

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.

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EFPIA Principles

- Platform – Company website or industry group website
- Reporting within 6 months of the end of the reporting period
- Aggregate by category but have itemized available
- Publicly available timeframe: disclosures shall remain in public domain for three years unless consent revoked or law calls for shorter time.

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EFPIA - Exemptions

- The following transfers of value are exempted from the disclosure requirement:
  1. Transfers of value that are solely related to over-the-counter medicines;
  2. Transfers of value such as items of medical utility, meals and drinks, samples; or
  3. Transfers of value that are part of ordinary course purchases and sales of Medicinal Products by and between a company and a healthcare professional (such as a pharmacists) or a healthcare orgnaisation which does not fall within the scope of the disclosure obligation.

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TOV Provisions: Template

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; itemization 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												
	Aggregate amount attributable to transfers of value to such Recipients - *Art. 3.02*					N/A	N/A	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*		*Optional*
	Number of Recipients in aggregate disclosure - *Art. 3.02*					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. 3.02*					N/A	N/A	%	%	%	%		N/A
HCOs	***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, 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*
	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*					*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*		*Optional*
	Number of Recipients in aggregate disclosure - *Art. 3.02*					*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. 3.02*					%	%	%	%	%	%		N/A

R &D	***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

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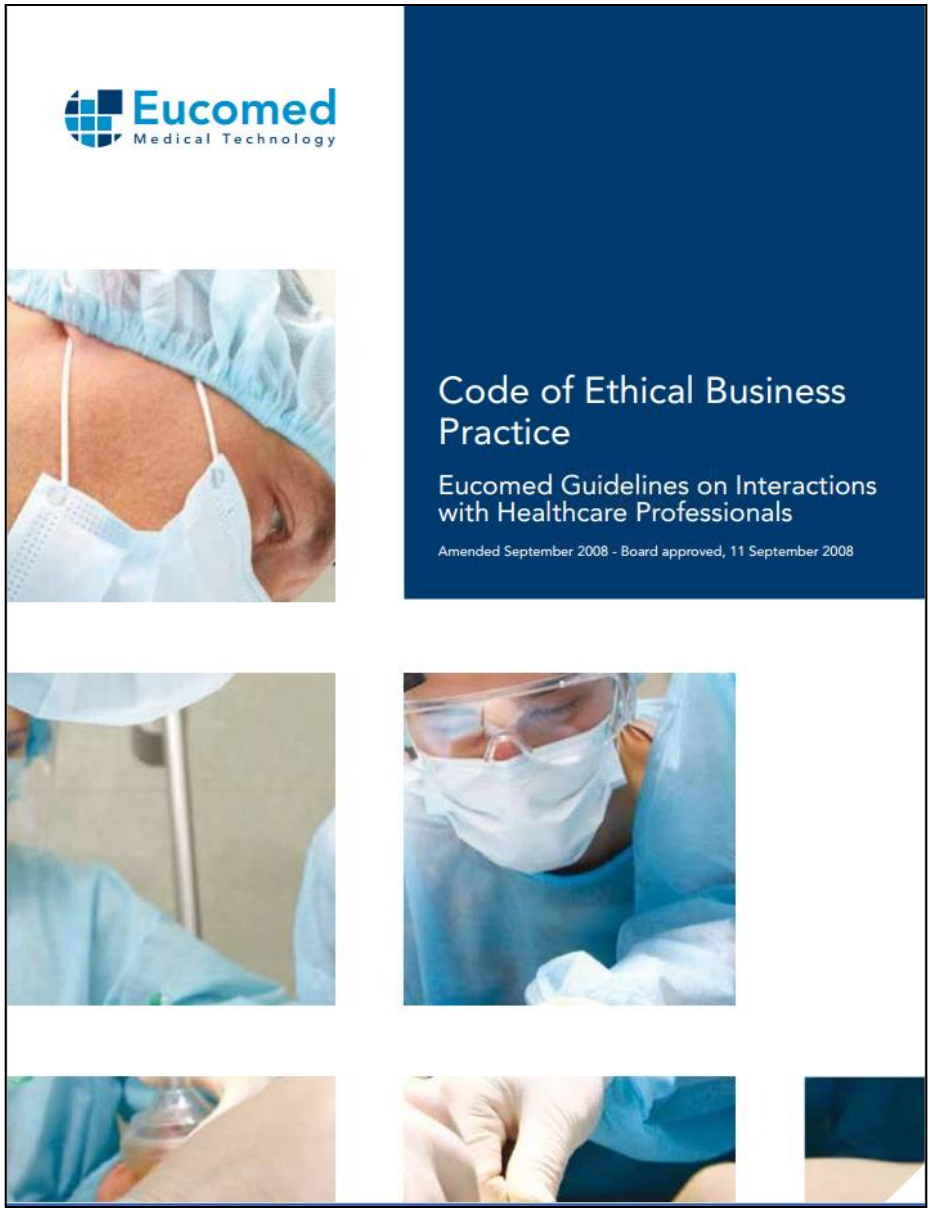

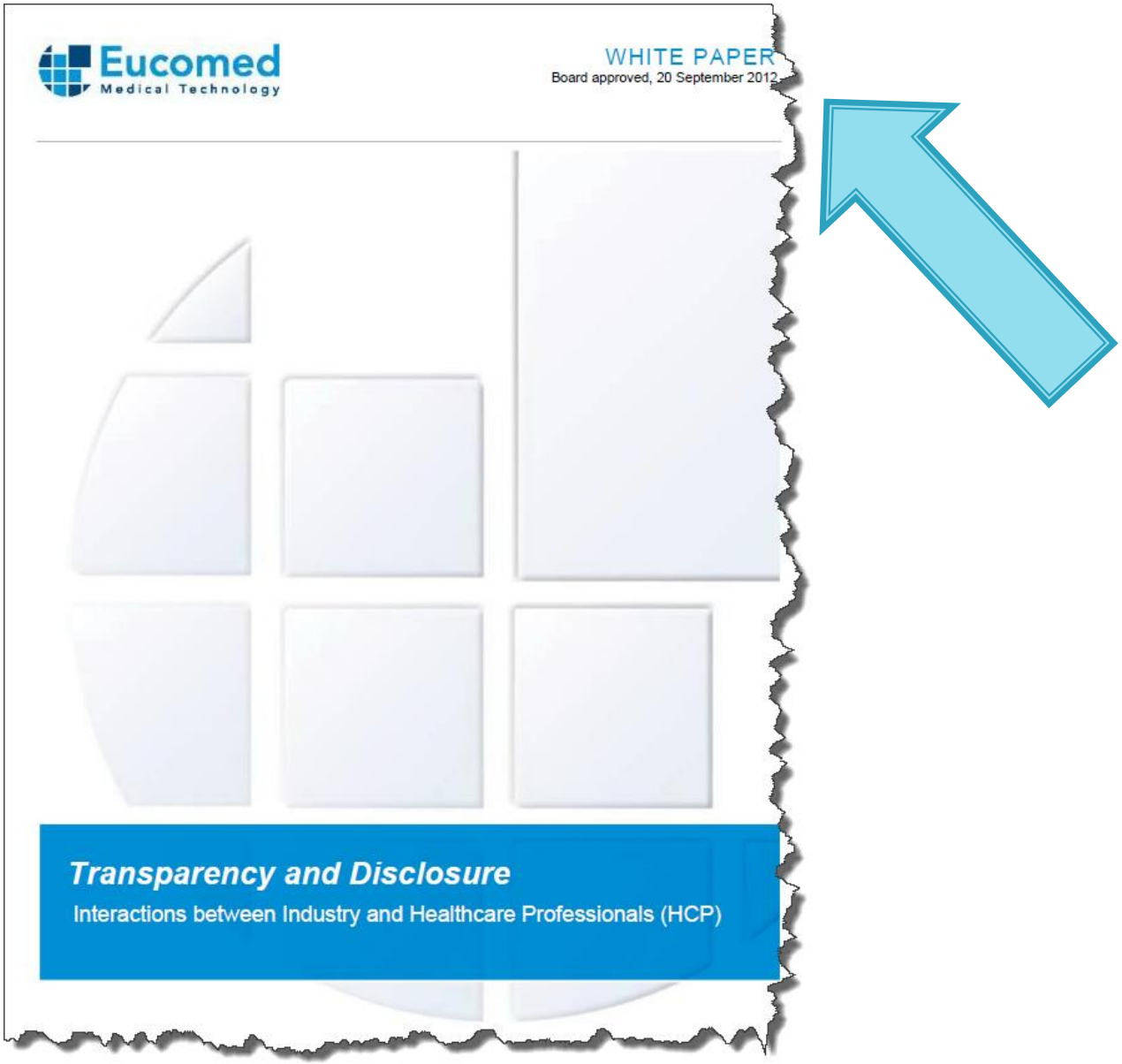

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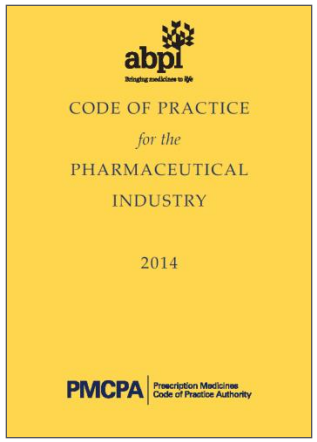
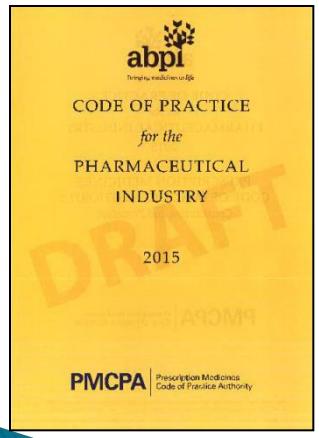
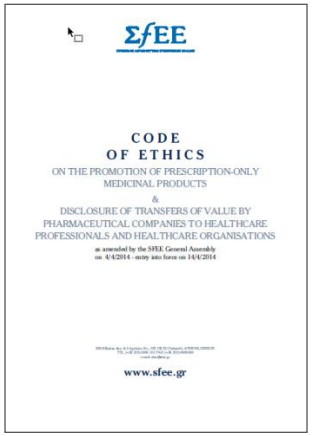
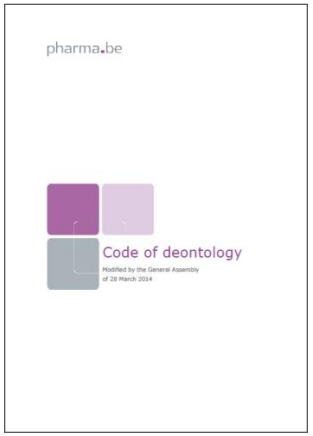
Pharmaceutical Industry Group Codes

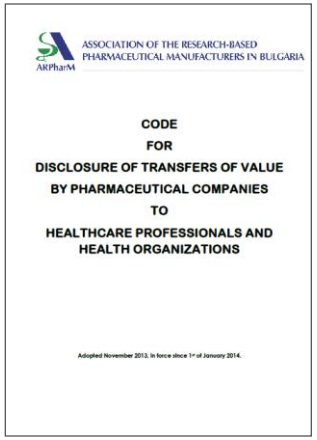


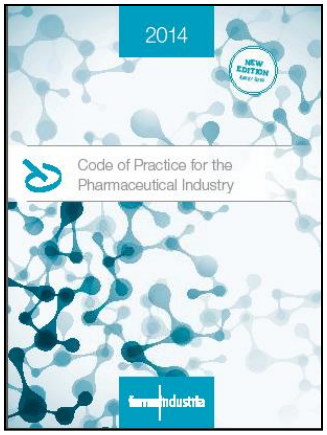
2015

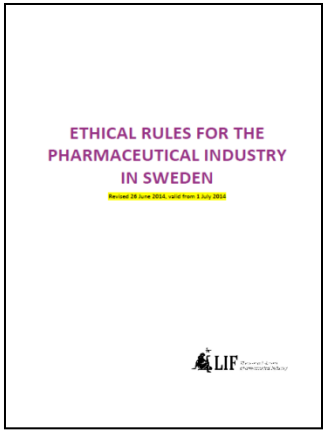




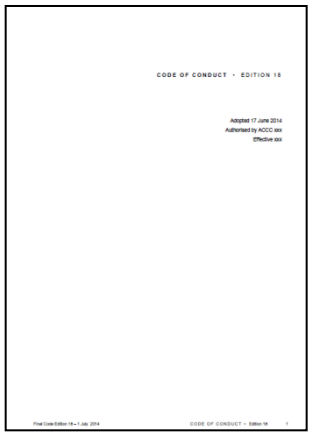








2015



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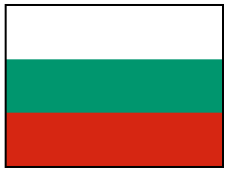
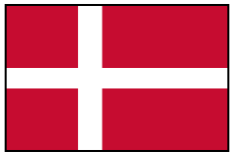
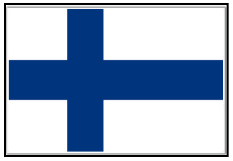
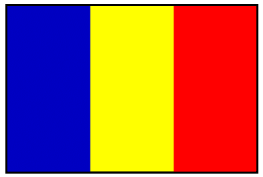
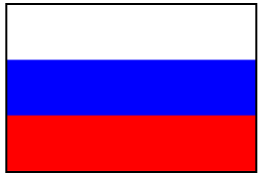
Challenge: Language

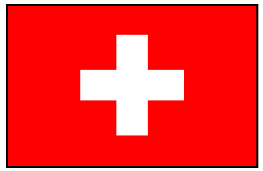



Country	Required Reportable Language (s)
Austria	• German or • English
Belgium	• Dutch (required) • French (required) • English (encouraged)
Bulgaria	• Bulgarian
Czech Republic	• Czech (required) • English (required)
Finland	• Finnish
France	• French
Germany	• German
Romania	• Romanian
Russia	• Russian (required) • English (required)
Serbia	• Serbian (required) • English (recommended)
Slovenia	• Slovenian (required) • English (encouraged)
Sweden	• Swedish (required) • English (encouraged)
Switzerland	• English • French* • German* • Italian*



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Location of Disclosure

- EFPIA: On member company's website or on a central platform
  - Disclosures to be made on the member company's website (Austria, Estonia, Finland, Germany, Hungary, Italy, Poland, Spain, Switzerland, Slovenia);
  - Disclosures to be made on the national member association website/central platform (Czech Republic, Belgium, Greece, the Netherlands, United Kingdom);
  - Disclosures to be made on either the company's website or the national member association's website (Sweden, Turkey, Latvia, Croatia, Serbia, Russia, Ukraine);
  - Disclosures to be made on the company's website linked to the national member association's website (Bulgaria, Lithuania, Norway);
  - Disclosures to be made on the national member association's website linked to the company website (Cyprus, Romania);
  - Not yet identified (Ireland, Malta);
  - N/A (Denmark, France, Portugal, Slovakia).

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Challenge: Cross Border

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Challenge: Report Formats

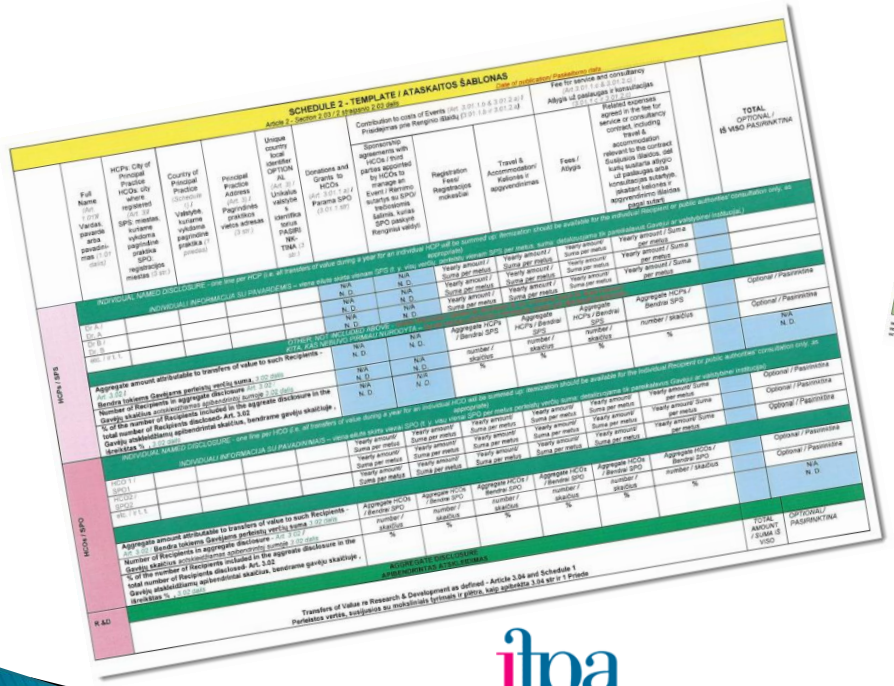
SCHEDULE 2 - TEMPLATE

Date of publication: .....

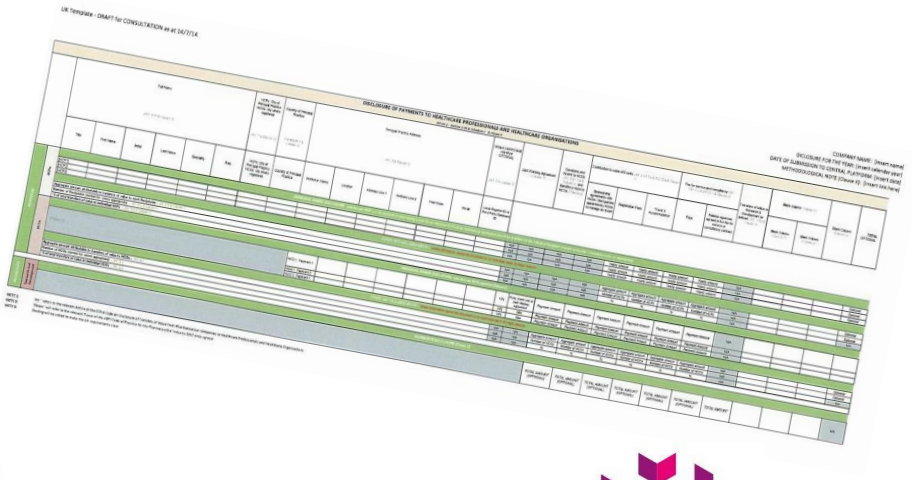
	Full Name (Art. 1.6)	HCPs: City of Principal Practice HCOs: city where registered (Art. 3)	Country of Principal Practice (Schedule 1)	Principal Practice Address (Art. 3)	Unique country identifier OPTIONAL (Art. 3)	Donations and Grants to HCOs (Art. 3.01.1.a)	Contribution to costs of Events (Art. 3.01.1.b & 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; itemization 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												
	Aggregate amount attributable to transfers of value to such Recipients - Art. 3.02					N/A	N/A	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs		Optional
	Number of Recipients in aggregate disclosure - Art. 3.02					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. 3.02					N/A	N/A	%	%	%	%		N/A
HCOs	*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, 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
	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					Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs		Optional
	Number of Recipients in aggregate disclosure - Art. 3.02					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. 3.02					%	%	%	%	%	%		N/A
R&D	*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

efpia



ifpa
INOVATYVIOS FARMACIJOS PRAMONĖS ASOCIACIJA



abpi
Bringing medicines to *life*

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Challenge: Consent

- Industry groups dealing with it in various ways
- Consent: Self-Regulation vs. Legislation

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EFPIA Fliers

Responsible Transparency

In 2016, EFPIA member companies and those members of our member associations will make public details of certain payments made to healthcare professionals (HCPs) and healthcare organisations (HCOs) during 2015. The purpose of this letter is to explain why we are taking this step, what it means for you and to ask for your support.

Collaborative working between healthcare professionals and commercial life sciences organisations has long been a positive driver for advancements in patient care and progression of innovative medicine. Both parties regularly join together, during early scientific research, clinical trials and medical education in the interest of delivering and advancing high quality patient care.

Through the introduction of codes of conduct and other initiatives, the industry and healthcare professionals have worked together to continuously enhance the standards underpinning their relationship. However, this is an ongoing process and we are now taking the next step.

In recent years there has been growing public interest in the nature of the pharmaceutical industry's relationships with both HCPs and HCOs. Critically, the public want to know that such relationships do not influence clinical decisions, that they can trust their HCP **to recommend, administer or purchase appropriate care and treatments based solely on clinical evidence and experience.**

The European Commission recognises the need for good governance in the pharmaceutical sector and to this end published the Tajani Guiding Principles for the Promotion of Good Governance in the Pharmaceutical Industry signed off by all stakeholders in 2013. These Principles set out the expectation that **all financial interactions should be fully transparent.** The concern for improved transparency at EU level is reflected in actions at Member State level.

EFPIA, along with its member companies, fully support these principles and have responded to this with the publication of the EFPIA HCP/HCO Disclosure Code and associated amendments to the EFPIA HCP Code. This Disclosure Code, which has been transposed into national codes, requires that all member companies to make payments to HCPs and HCOs in certain categories publicly available from 2016. The transactions disclosed could consist of, for instance, a grant to a HCO, a consultancy fee for speaking or, payment for travel, or registration fees to attend a medical education congress. This information will be published on a public platform, which could be on the company's own website or a central platform.

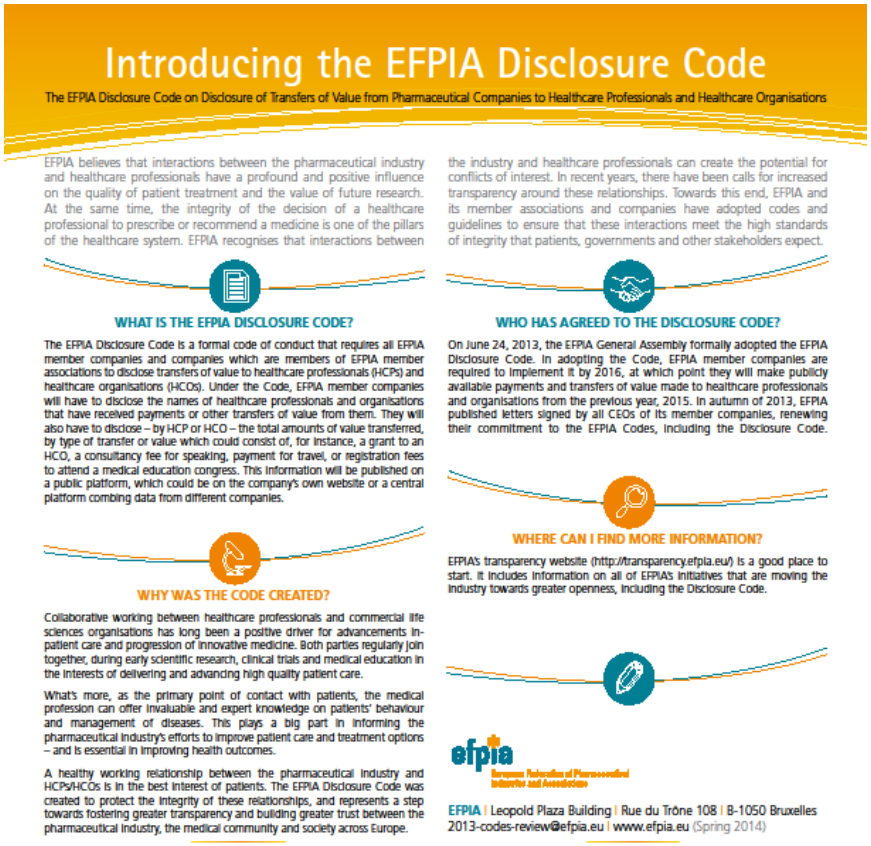
However, **the ultimate success of this initiative**, as measured by public acceptance, depends in large part on the industry and HCP community working in partnership. We wish to ensure that our interactions with the profession are well understood and accepted by healthcare stakeholders and the public at large. Only if we work together can we successfully enhance transparency and public trust in our mutual relationship. Therefore we ask that you, as a healthcare professional, give your support to this initiative.

Over the next two years **we will keep you informed of progress on the implementation of the Disclosure Code** via the website of our member association in your country.
The Disclosure Code itself can be accessed at http://transparency.efpia.eu/. We also encourage you to ask questions and provide comments (provide details of contact point). We will be providing a detailed set of explanatory Q&A in the near future, which we hope will answer many of your questions.

In closing, we would like to emphasize that **our goal is to strengthen the legitimate relationship between pharmaceutical companies and healthcare professionals by making these more transparent** and therefore better understood by patients and other stakeholders. We look forward to continuing working with you to improve the quality of patient treatment, research and overall patient care.

efpia

EFPIA | European Federation of Pharmaceutical Industries and Associations
Leopold Plaza Building | Rue du Trône 108 | B-1050 Bruxelles
reception@efpia.eu | www.efpia.eu (Spring 2014)



Introducing the EFPIA Disclosure Code

The EFPIA Disclosure Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations

EFPIA believes that interactions between the pharmaceutical industry and healthcare professionals have a profound and positive influence on the quality of patient treatment and the value of future research. At the same time, the integrity of the decision of a healthcare professional to prescribe or recommend a medicine is one of the pillars of the healthcare system. EFPIA recognises that interactions between the industry and healthcare professionals can create the potential for conflicts of interest. In recent years, there have been calls for increased transparency around these relationships. Towards this end, EFPIA and its member associations and companies have adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments and other stakeholders expect.

WHAT IS THE EFPIA DISCLOSURE CODE?

The EFPIA Disclosure Code is a formal code of conduct that requires all EFPIA member companies and companies which are members of EFPIA member associations to disclose transfers of value to healthcare professionals (HCPs) and healthcare organisations (HCOs). Under the Code, EFPIA member companies will have to disclose the names of healthcare professionals and organisations that have received payments or other transfers of value from them. They will also have to disclose – by HCP or HCO – the total amounts of value transferred, by type of transfer or value which could consist of, for instance, a grant to an HCO, a consultancy fee for speaking, payment for travel, or registration fees to attend a medical education congress. This information will be published on a public platform, which could be on the company's own website or a central platform combing data from different companies.

WHY WAS THE CODE CREATED?

Collaborative working between healthcare professionals and commercial life sciences organisations has long been a positive driver for advancements in-patient care and progression of innovative medicine. Both parties regularly join together, during early scientific research, clinical trials and medical education in the interests of delivering and advancing high quality patient care.

What's more, as the primary point of contact with patients, the medical profession can offer invaluable and expert knowledge on patients' behaviour and management of diseases. This plays a big part in informing the pharmaceutical industry's efforts to improve patient care and treatment options – and is essential in improving health outcomes.

A healthy working relationship between the pharmaceutical industry and HCPs/HCOs is in the best interest of patients. The EFPIA Disclosure Code was created to protect the integrity of these relationships, and represents a step towards fostering greater transparency and building greater trust between the pharmaceutical industry, the medical community and society across Europe.

WHO HAS AGREED TO THE DISCLOSURE CODE?

On June 24, 2013, the EFPIA General Assembly formally adopted the EFPIA Disclosure Code. In adopting the Code, EFPIA member companies are required to implement it by 2016, at which point they will make publicly available payments and transfers of value made to healthcare professionals and organisations from the previous year, 2015. In autumn of 2013, EFPIA published letters signed by all CEOs of its member companies, renewing their commitment to the EFPIA Codes, including the Disclosure Code.

WHERE CAN I FIND MORE INFORMATION?

EFPIA's transparency website (http://transparency.efpia.eu/) is a good place to start. It includes information on all of EFPIA's initiatives that are moving the industry towards greater openness, including the Disclosure Code.

efpia
European Federation of Pharmaceutical Industries and Associations

EFPIA | Leopold Plaza Building | Rue du Trône 108 | B-1050 Bruxelles
2013-codes-review@efpia.eu | www.efpia.eu (Spring 2014)

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Pharmadisclosure.eu

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United Kingdom

- Current System: Annual aggregate reporting; individual HCPs are not named.
- Earlier this year, ABPI, the British pharmaceutical industry group reported that in 2013 its member companies spent approximately £38.5m on support in 2013.
- After EFPIA adopted the Disclosure Code, the ABPI transposed those disclosure provisions into its own Code.
- However, in July 2014 the ABPI announced it would be amending its Code, including aspects of its disclosure provisions. The amended Code is expected to be adopted later this year. Although largely similar to EFPIA's disclosure provisions, there are some key differences:
  - Additional categories of reporting;
  - HCOs reported on per activity basis;
  - More information required by template.

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Netherlands

- Individual-level reporting that pre-dates the adoption of EFPIA's Code; first reports in 2013 to cover 2012 data
- Inspired by US Sunshine Act
- Disclose service agreements; sponsorship agreements; and support for patient organisations
- Unlike EFPIA, 500 euro threshold for reporting
- Central register, www.transparentiergesiter.nl, searchable by HCP but not by pharmaceutical company

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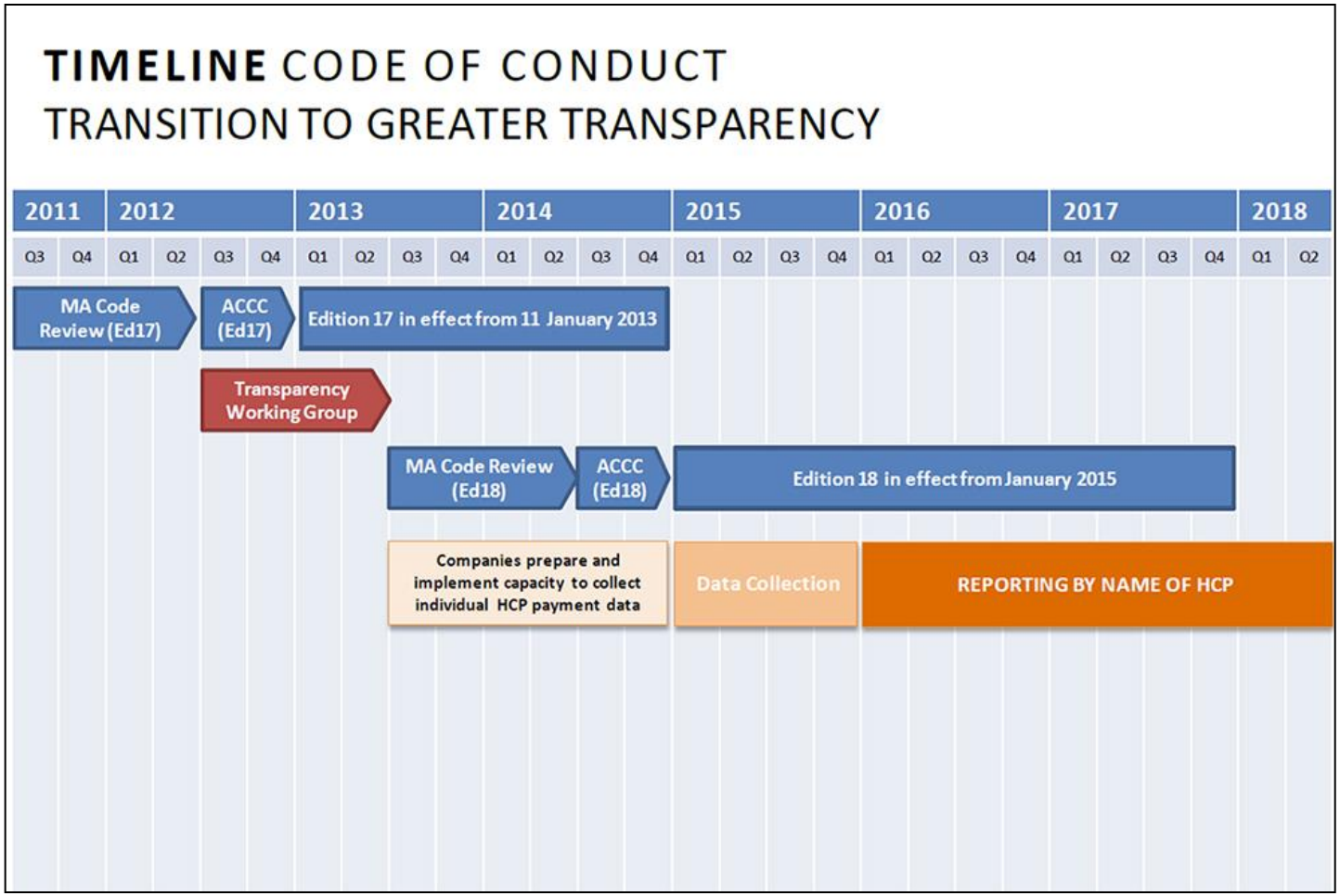
Australia



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Reporting Requirements

- Beginning on October 1, 2015, the following transfers of value to HCPs (HCPs are defined in the Code's glossary in the following manner: "a healthcare professional registered to practice in Australia who in the course their professional activities may prescribe, dispense, recommend, supply or administer a prescription medicine in Australia") must be reported:
  - Fees paid to HCPs in return for speaking at an educational meeting or event.
  - Sponsorship of a HCP to attend an educational event. Specific reportable items in regard to sponsorships are any airfare, accommodation or registration fees directly in association with the meeting, whether held inside or outside of Australia.

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Reporting Requirements

- **Reporting format**: Companies must report the aforementioned transfers of value pursuant to a template provided in the Code's Guidelines. In the template,companies will be required to report all individual transfers of value for each HCP, indicating the following information:
  - Date of the event or provision of service;
  - HCP's name;
  - Type of HCP (e.g., medical practitioner, pharmacist, nurse practitioner);
  - HCP's principal practice address;
  - Description of the service (e.g., speaker; Advisory Board; etc.);
  - Description of the event (e.g., company sponsored meeting in Australia; independent meeting held in Australia; independent meeting held overseas; etc.);
  - Whether the payment was made to the HCP or a third party;
  - The amount of the payment or transfer of value, subdivided into (where relevant) registration fees, travel and accommodation, and fees for service.

Reporting Requirements continued

- Fees paid to HCP consultants in Australia, or to their employers on their behalf, for specific services rendered by them. Such services include, but are not limited to: all consultancy services provided in relation to educational meetings; preparation of promotional materials or product position papers; assistance with training; or any other advice to the company. Reportable items include all payments in respect to consulting fees, accommodation and airfares (both within and outside Australia) associated with the provision of consulting services.
  - **Such services do not include payments to consultants in relation to research and development work, including the conduct of clinical trials.** (Research and development is defined in the Code's glossary as follows: "any early-stage research, such as target discovery, drug discovery, mechanism of action or proof of concept studies; pre-clinical research, such as toxicological studies; and human clinical trials".)
- Fees paid to HCPs in their role as Advisory Board members. Specific reportable items include all payments with respect to Advisory Board sitting fees, accommodation and airfares (both within and outside Australia) associated with the activities of the Advisory Board.
- Fees paid to HCPs for the purpose of market research. Such fees must be reported when the company knows the identity of the HCP. Reporting is **not** required where the company contracting the marketing research is not involved in the selection of the participating HCPs and is not aware of the identities of the participating HCPs.
- Payment of an educational grant or sponsorship to a specific HCP.

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Method of Publication

- **Where is the report published**: Each company must place its transparency report on its own website. Medicines Australia will provide hyperlinks to each company's report from its website.
- **Timing**: The initial reports – which cover the period from October 1, 2015–April 30, 2016 -- must be published on company websites by August 31, 2016, and every 6 months thereafter. The reporting cycle is a six-month cycle (except for the initial report, which covers seven months).
- **Consent**: HCPs must consent to disclosure of payment information. If they do not, companies must report such transfers in the aggregate.

- **Declaration**: The most senior executive officer of the member company must provide to Medicines Australia a signed and dated declaration that the company has published the required report with the required information on its company website. The declaration must be provided to Medicines Australia within 7 calendar days following publication of each report. (In the Glossary to the Code, "senior executive officer" is defined as follows: "'senior executive officer' means the most senior executive officer of the member whether described as Managing Director, Chief Executive Officer, General Manager, Regional Director or otherwise …. For a non-member company this means the most senior executive responsible for the company's prescription medicines business.").

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Exemptions

- Transfers of value only have to be reported that are related to prescription medicines. Companies that have separate divisions that do not supply prescription medicines for human use (e.g., animal health divisions) are only required to report transfers of value in relation to the human use prescription medicines.
- Companies do not have to report transfers of value made to their employees who are HCPs.
- Hospitality (food and beverages) does not have be reported. The cost of any meal (including drinks) provided by a company must be below the defined limit included in the Code ($120 for food and beverages, exclusive of GST).
- Venue costs are not reportable (e.g., room and/or AV equipment hire).
- Airport ground transfers, taxis, parking fees.
- Research and development.

Sponsorship

- The Australia Code has created a different reporting system for sponsorship of third party educational meetings and symposia (e.g., financial sponsorship of a third party educational event; monetary contribution to support the conduct of grand rounds, clinic meetings or journal club meetings; purchase space for providing a trade display at an educational event). Beginning on October 1, 2015, the following requirements apply to company reporting of such events organized by third parties:
  - Companies must complete the table set forth in the Code's appendix for each six month period of November 1 through April 30 and May 1 through October 31.
  - Companies must provide the completed table to Medicines Australia within four months from the end of each six-month period.
  - The initial report will cover seven months – October 1, 2015 through April 30, 2016 –but subsequent reports will follow the six-month reporting cycle.
  - Medicines Australia will make publicly available on its website the completed reports provided by each member company within 2 months from when the reports are submitted to Medicines Australia.

Japan Transparency Requirements

The Japan Pharmaceutical Manufacturers Association (JPMA)

"JPMA Guidelines on Transparency on Corporate Activities with Medical Institutions and Healthcare Professionals"

Japanese Federation of Medical Devices Association (JFMDA)

"Transparency Guidelines for the Medical Device Industry, and its Relationships with Medical Institutions and Other Organisations"

Requires:

1. JPMA member companies to establish transparency policy based on JPMA guidelines
2. JPMA member companies to publicly disclose payments to Medical Institutions and HCPs
   - Data will be uploaded on company's own website

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Japan Transparency Requirements

Payments to be disclosed:

- R&D-related costs
- Grants/Donations
- Honoraria (Speaking, Writing, & Consulting)
- Information Exchange Costs (i.e. speaker programs)
- Meals and Hospitalities Provided to HCPs

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Do Start Believin'

The US was super fun, now's the time for the world to get the sun
Watch the global trend, goin' everywhere
Just another report –transparency we must support
Watch the global trend, goin' everywhere

A worker in an EFPIA room, concerned about France and impending doom
For a TOV you must disclose, it goes on and on and on and on

Companies reporting , up and down the continent
Their compliance working through the night
Compliance people convertin' foreign languages
Trackin' spend and country lines

Workin' hard to get the OK, HCPs can consent or no way
Praying the reports go all right – Just one more form
Some will sign, Some will not, Some will sign then revoke
Oh, the reports never end, It goes on and on and on and on

Templates waiting, For recipient spend, their KOLs consenting
Across the globe, Compliance people
Research and development spend, separate in the aggregate

Do start believin', hold on to that feelin'
Compliance people, do start believin'
Hold on, compliance people
Do start believin'
Hold on to that feelin'– Compliance people

PORZIO LifeSciences

Contact Information

Brian P. Sharkey

Director

Porzio Life Sciences, LLC.

973-889-4314

bpsharkey@pbnlaw.com

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