The EFPIA HCP / HCO Disclosure Code

& transposition example

Global Code Update Roundtable

Latin American Pharmaceutical and Medical Device Compliance Congress

México D.F., 29 de Julio 2014

European Federation of Pharmaceutical Industries and Associations

www.efpia.eu

Living up to expectations

The R&D-based pharmaceutical industry is committed to **working in partnership with all stakeholders** to improve healthcare across Europe.

Industry is conscious of the importance of **providing accurate, fair and objective information** about its medicines to allow rational decisions to be made about their use. As such, industry fully respects the role that (EU) legislation plays in regulating interactions between pharmaceutical companies and healthcare professionals.

In the same spirit, **industry is committed to working towards greater transparency, accountability and ethical behaviour within an industry framework of self-regulation**.

Therefore, EFPIA will continue to develop additional guidance around areas where **industry's credibility** is engaged.

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EFPIA's "Transparency" Initiative

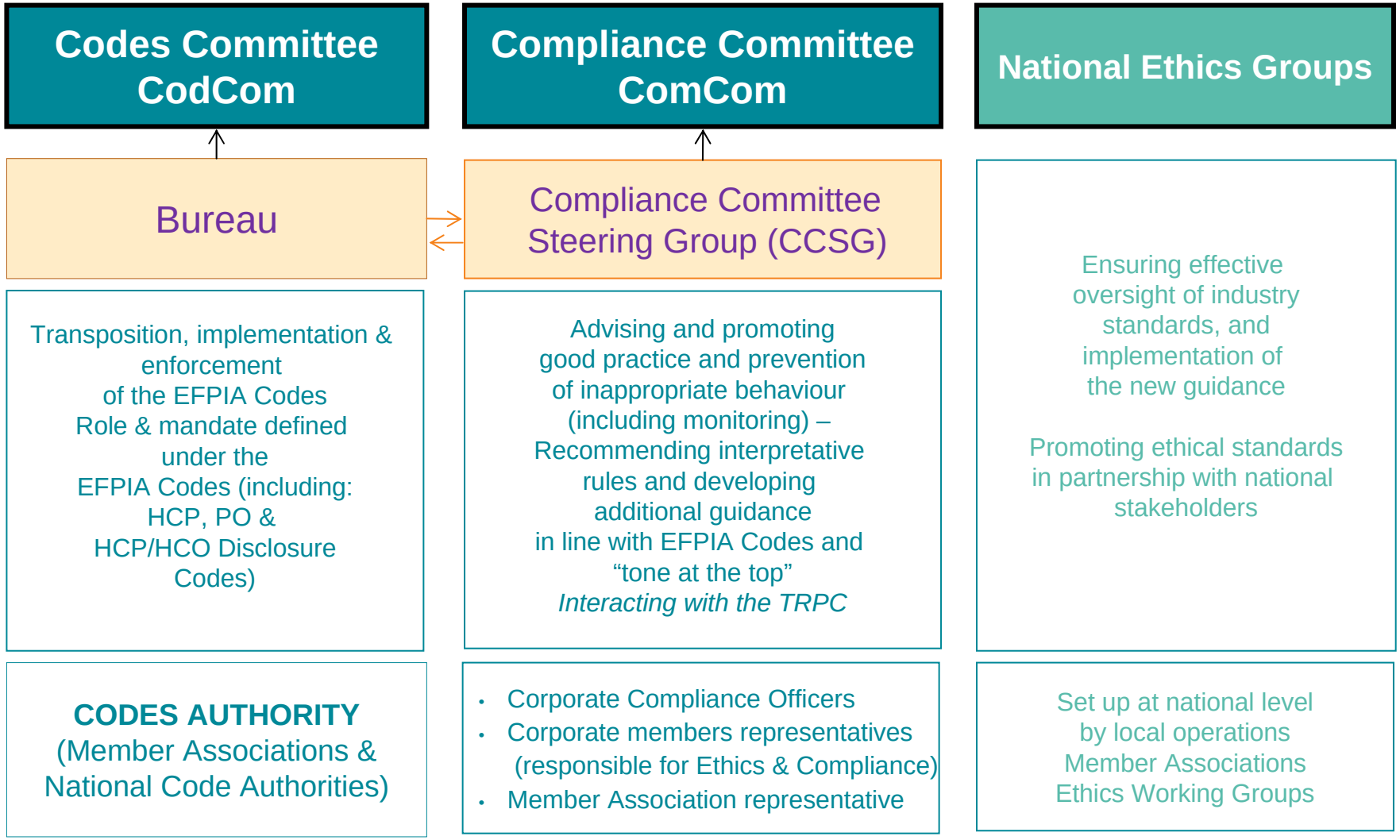
Increased external scrutiny of interactions between pharmaceutical companies and HCPs at national level:

- Legal provisions: Denmark, France, Portugal, Slovakia
- Self-regulatory provisions: the Netherlands, UK
- Disclosure activities outside Europe: Japan, US

Different approaches are in place at national level re communication to public authorities and/or publication on publicly accessible websites.

By acting now, EFPIA has the opportunity to help encourage a consistent approach to data disclosure in Europe and help guide further action at national level.

Code-Related Issues



Disclosure Requirements

THE EFPIA DISCLOSURE CODE

The EFPIA "Disclosure Code" was approved by the General Assembly on June 24th 2013

EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations *the "EFPIA HCP/HCO Disclosure Code"*

- **Each member company shall document and disclose Transfers of Value it makes, directly or indirectly, to or for the benefit of a HCP/HCO Recipient**
- **The first Reporting Period shall be the calendar year 2015** (disclosure in 2016)
- **Each member association shall transpose the provisions of this Code into its national code by 31 December 2013**
- **The Code sets out the minimum standards applicable to Member Associations, expect where it is in conflict with applicable national law or regulation, in which case deviations are allowed, but only to the extent necessary to comply with such national law or regulation**
- **The EFPIA Codes Committee shall assist Member Associations to comply with their obligations**

Compliance with the new Disclosure Code has become an obligation for membership – *this obligation will be reflected in the EFPIA Internal Rules.*

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Concomitant review of the HCP Code

- When preparing the new Code, it has been advised that EFPIA should include stricter rules on hospitality and gifts.

- The amendments to the HCP Code include:
  - The requirement for member associations to include a threshold on hospitality in their national codes; and
  - The prohibition of gifts.

Amendments to the HCP Code

GIFTS *Previously Article 10*	No gift or pecuniary advantage (in cash or benefit in kind) may be supplied, offered or promised to a healthcare professional.
INFORMATIONAL & EDUCATIONAL MATERIALS, and ITEMS OF MEDICAL UTILITY *New Article*	1. The transmission of informational or educational materials is permitted provided it is: (i) "inexpensive"; (ii) directly relevant to the practice of medicine or pharmacy; and (iii) directly beneficial to the care of patients. 2. Items of medical utility aimed directly at the education of healthcare professionals and patient care can be provided if they are inexpensive and do not offset routine business practices of the recipient. 3. EFPIA and Member Associations shall provide guidance on the meaning of the term "inexpensive", as used in this Article 8. Companies must comply with any relevant guidance provided under this Section 8.03 or in connection with any Applicable Code(s).
HOSPITALITY *Addition to Article 9*	Member Companies shall not provide or offer any meals (food and beverages) to healthcare professionals, unless, in each case, the value of such meals (food and beverages) does not exceed the monetary threshold set by the relevant Member Association in its national code. Each Member Association shall set such monetary threshold in its national code by 31 December 2013, failing which EFPIA will set such threshold in lieu of such Member Association.

The amendments will be included in the coordinated version of the HCP Code.

Final “Disclosure” Code

Approved by the General Assembly of 24 June 2013

Preamble

Applicability of the Code

Applicable Law or Regulation

Article 1 – Disclosure Obligation

Article 2 – Form of Disclosure

Platform of Disclosure

Applicable National Code

Article 3 – Individual and Aggregate Disclosure

Methodology: each member company will publish a note summarising the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category of disclosure

Article 4 – Enforcement

Article 5 – Amendments to, and Guidance Regarding Compliance with the Code

Schedule 1 – Definition of Terms

Schedule 2 – Model of Standardised Template

Schedule 3 – Implementation and Procedure Rules

Preamble

- Healthcare professionals (HCP) and organisations (HCO) with whom they work provide the pharmaceutical industry with **valuable, independent and expert knowledge derived from their clinical and management experience**.
- EFPIA believes that interactions between pharma companies and HCP – either directly or through HCO – have a **profound and positive influence on the quality of patient treatments and the value of future research**.
- At the same time, the **integrity of the decisions** of a HCP to prescribe a medicine is one of the pillars of the healthcare system.
- EFPIA and its member associations have adopted codes and guidelines to ensure that these interactions meet the **high standards** of integrity that patients, governments and other stakeholders expect.
- **The society has a growing expectation that interactions between corporations and HCP/HCO are not only conducted with integrity but are also transparent.**

Applicability of the EFPIA Codes

The EFPIA membership, including:

- Corporate Member Companies (including full and affiliate members);
- Members of the EFPIA Specialised Groups: (i) European Bio-pharmaceutical Enterprises (EBE); and (ii) Vaccines Europe (VE);
- Member Companies of Member Associations that are not directly members of EFPIA.

EFPIA Member Associations (in 33 countries) are responsible for implementation and enforcement at national level.

For EFPIA direct membership, separate entities belonging to the same multinational company – which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation – shall be deemed to constitute a single company, and is as such committed to compliance with the EFPIA Codes.

Minimum standards at European level

- This Code sets out the **minimum standards** which EFPIA considers must apply to all EFPIA Member Associations in all member states.

- All EFPIA Member Associations are required to **transpose this Code into their national codes in full by 31 December 2013**, except where its provisions are in conflict with applicable national laws or regulations, in which case deviations are allowed, but only to the extent necessary to comply with such national law or regulation.

- Member Companies shall be bound by the relevant EFPIA Member Association's code in each country in Europe in which they operate (whether directly or through its relevant subsidiary).

Article1 – Disclosure Obligation

- **General Obligation:** each Member Company shall document and disclose Transfers of Value (ToV) it makes, directly or indirectly, to or for the benefit of a Recipient

- **Excluded Disclosures:**
  - ToV solely related to OTC
  - Items of medical utility
  - Meals & Drinks – subject to a threshold (review of HCP Code)
  - Medical Samples – subject to the “4x2” standard
  - ToV relating to purchasing and selling medicinal products

Article 2 – Form of Disclosure

- **Annual Disclosure Cycle** – first disclosure in 2016, for ToV in 2015; Reporting Period: full calendar year
- **Time of Disclosure** – within six months after the end of the relevant Reporting Period, first before mid-2016
- **Template** – Schedule 2, provided as a model, reflecting the requirements of the Code
- **Platform of Disclosure** – either on the Member Company's website, or on a central platform; disclosure to remain in the public domain for 3 years, subject to national laws and regulations
- **Applicable National Code** – disclosures shall be made pursuant to the national code of the country where the Recipient has his/her principal activity
- **Language of Disclosure** – local language, and English (recommended)
- **Documentation and Retention of Records** – 5 years retention, unless shorter period is required by national applicable laws and regulations

Article 3 – Individual & Aggregate Disclosure

Level of Disclosure	Disclosure Categories
Aggregate	**Research & Development** ToV to HCPs/HCOs related to the planning and conduct of: a.Non-clinical studies *(as defined in the OECD Principles of GLP)* b.Clinical trials *(as defined in Directive 2001/20/EC)* 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 *(cfr Section 15.02 of the EFPIA HCP Code)*
Individual HCO ***"following the money"***	**Donations & Grants to HCOs** **Contribution to costs of events** ➢Sponsorship agreements with HCOs/third parties appointed by HCOs to manage an event ➢Registration fees ➢Travel & accommodation **Fee-for-service & consultancy** ➢Fees ➢Related expenses agreed in the fees for service or consultancy contract
Individual HCP ***"following the money"***	**Contribution to costs of events** ➢Registration fees ➢Travel & accommodation **Fees for service & consultancy** ➢Fees ➢Related expenses agreed in the fees for service or consultancy contract

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).

Transfers of Value re Research & Development

Transfers of Value to HCP/HCO relating to Research & Development must be disclosed in aggregate.

Such Transfers of Value to the planning or conduct of:

- non-clinical studies (as defined in *OECD Principles on Good Laboratory Practice*);
- clinical trials (as defined in Directive 2001/20/EC); or
- 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.

Transfers of value that do not fall within the definition of “Research and Development Transfers of Value” shall be disclosed under the category “fee for service and consultancy”.

Article 4 – Enforcement

- **Enforcement through Member Associations** – each Member Association shall adopt implementation and Procedure Rules which will be binding upon its members, in a manner that is consistent with applicable data protection, competition, and other applicable laws and regulation.

  When transferring values to HCP/HCO, and in their written contracts with HCP/HCO, companies are encouraged to include provisions regarding to consent of the Recipients to consent to disclosure of the transfers of value in accordance with the provisions of the EFPIA HCP/HCO Disclosure Code. In addition, companies are encouraged to renegotiate existing contracts at their earliest convenience to include such consent to disclosure.

- **Disclosure Requirements Different from this Code** – disclosures requirements different from those in this Code shall be clearly and conspicuously identified; deviations are only allowed to the extent necessary to comply with national laws and regulations.

  The Codes Committee will submit a report to the Board, and the General Assembly will confirm consistency with the Code.

Schedule 2 – Model 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

Disclosure Transposition Process - Spain

Art. 18 Transparency in Industry's Relationships

WHO	All companies member of Farmaindustria and/or that signed on the Code
WHAT	All Transfers of Value, direct and indirect enacted the previous year
RECIPIENTS	Individual Healthcare Professionals and Healthcare Organisations
WHEN	By de end of the first semestre of each applicable period. 2016 will be the first period (Publication by 01.07.2016, of 2015 data)
HOW	Standard template for all companies Each company will attach a methodological note to the information In Spanish. Additionally, publication in English is recommended

Identifying each HEALTHCARE PROFESSIONAL*	▪ **Related to Educational Activities and Scientific-Professional Meetings** ‣ Registration fees ‣ Travel and accomodation ▪ **Related to Fees for Service** ‣ Fees ‣ Related expenses, including travel and accommodation
Identifying each HEALTHCARE ORGANISATION	▪ **Donations** ▪ **Related to Educations Act. and Scientific-Professional Meetings** ‣ Sponsorship HCOs / third parties appointed to manage Events ‣ Registration fees ‣ Travel and accomodation ▪ **Related to Fees for Service** ‣ Fees ‣ Related expenses, including travel and accomodation
AGGREGATE	**Research and Development**

* If, for legal reasons, individual publication cannot take place, it will be given in aggregate form

WHERE	In the Spanish or European website of the company Link from Farmaindustria's Self-Regulation System website
AVAILABILITY	Data shall remain available during a minimum of 3 years. Each company shall keep record of the data for a minimum of 5 years.

Art. 18 Transparency in Industry's Relationships

- To strengthen compliance with disclosure obligations, companies shall provide the information yearly to the Code Surveillance Unit.

- Transfers of Value to HCP/HCO related to **Research and Development** shall be published in an aggregate form.

  - Non-clinical studies (as defined by the *OECD Principles on Good Laboratory Practice*);
  - Clinical trials (as defined by Directive 2001/20/EC); or
  - Post-authorization studies (considered in article 14.2 of the Code).

- Transfers of Value that do not fall within the scope of the definition of "Transfers of Value related to Research and Development" shall be published under the category "Fees for Service".

Annex I – Model Template

CODIGO DE BUENAS PRÁCTICAS DE LA INDUSTRIA FARMACÉUTICA 2014
ANEXO I - Plantilla de Recogida de Información
Propuesta para aprobación por los Órganos de Gobierno de FARMAINDUSTRIA en Junio de 2014

	Nombre Completo (Obligatorio) (Art. 18.1)	Profesionales Sanitarios (PS): ciudad de ejercicio profesional Organizaciones Sanitarias (OS): ciudad de domicilio social (Obligatorio) (Art. 18.3)	País de ejercicio profesional (Opcional) (Art. 18.3)	Dirección Profesional (Opcional) (Art. 18.3)	DNI / CIF XXX1234XX (Obligatorio) (Art. 18.3)	Donaciones (Art. 18.3.1.a)	Actividades formativas y reuniones científico-profesionales (Art. 18.3.1.b & 18.3.2.a)			Prestación de servicios (Art. 18.3.1.c & 18.3.2.b)		TOTAL
							Colaboraciones/ patrocinios con OS / terceros asignados por OS para la gestión de Eventos	Cuotas de inscripción	Desplazamiento y Alojamiento	Honorarios	Gastos relacionados acordados contractualmente para la prestación de estos servicios, incluyendo traslados y alojamiento	
Profesionales Sanitarios (PS)	PUBLICACIÓN NOMINATIVA INDIVIDUAL: Las Transferencias de Valor realizadas anualmente a título individual a cada Profesional Sanitario se sumarán de forma que se publique una cantidad por cada Profesional Sanitario individual. El desglose únicamente estará disponible para su consulta, cuando proceda, por parte del Profesional Sanitario individual, los Órganos de Control del Código o de las autoridades competentes.											
	DR. AAAA					No aplica	No aplica	Importe Anual €	Importe Anual €	Importe Anual €	Importe Anual €	Opcional
	DR. AAAB					No aplica	No aplica	Importe Anual €	Importe Anual €	Importe Anual €	Importe Anual €	Opcional
	etc.					No aplica	No aplica	Importe Anual €	Importe Anual €	Importe Anual €	Importe Anual €	Opcional
	INFORMACIÓN NO INCLUIDA ARRIBA - información que por razones legales no puede publicarse de forma individual											
	Importe agregado imputable a las Transferencias de Valor realizadas a PS - Artículo 18.4					No aplica	No aplica	Importe Agregado Anual €	Importe Agregado Anual €	Importe Agregado Anual €	Importe Agregado Anual €	Opcional
	Número de PS cuya información se publica en agregado - Artículo 18.4					No aplica	No aplica	Número PS	Número PS	Número PS	Número PS	Opcional
	% que representan sobre el total de PS que han recibido Transferencias de Valor - Artículo 18.4					No aplica	No aplica	%	%	%	%	No Aplica
Organizaciones Sanitarias (OS)	PUBLICACIÓN NOMINATIVA INDIVIDUAL: Las Transferencias de Valor realizadas anualmente a título individual a cada Organización Sanitaria se sumarán de forma que se publique una cantidad por cada Organización Sanitaria individual. El desglose únicamente estará disponible para su consulta, cuando proceda, por parte de la Organización Sanitaria individual, los Órganos de Control del Código o de las autoridades competentes.											
	ORG. SANIT 1					Importe Anual €	Importe Anual €	Importe Anual €	Importe Anual €	Importe Anual €	Importe Anual €	Opcional
	ORG. SANIT 2					Importe Anual €	Importe Anual €	Importe Anual €	Importe Anual €	Importe Anual €	Importe Anual €	Opcional
	etc.					Importe Anual €	Importe Anual €	Importe Anual €	Importe Anual €	Importe Anual €	Importe Anual €	Opcional
Investigación y Desarrollo	PUBLICACIÓN AGREGADA											
	Transferencias de Valor relacionadas con Investigación y Desarrollo - Artículo 18.6											Importe Anual €

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