Deloitte.

Global transparency study — Life sciences

A call to action for compliance

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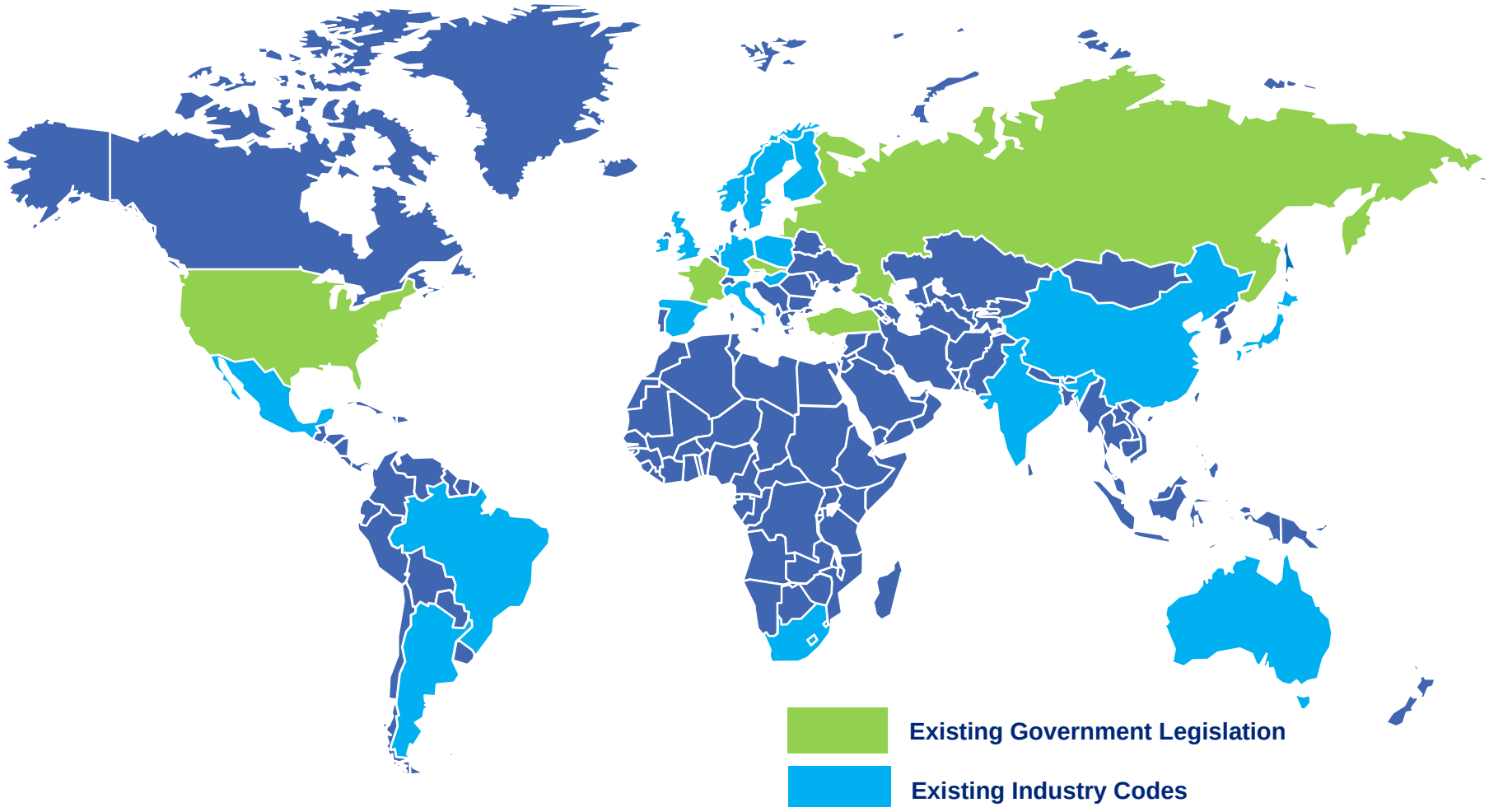
Agenda

- International legislation and codes
- Global HCP transparency study
- Examples to global HCP transparency approach and governance model
- Challenges facing Global HCP transparency programs
- Global HCP transparency landscape

International legislation and codes

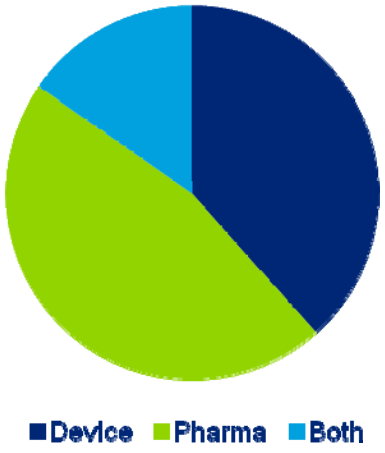


Transparency regulations span the globe and there are minor differences in scope and definitions across the regulations

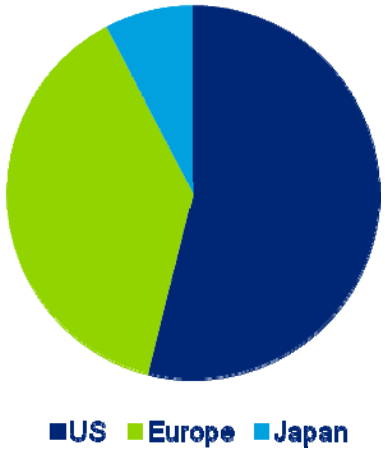
Global HCP transparency study methodology

1. Scope of Survey
   - April – June 2012
   - Twelve Life Sciences Companies
   - Interviews with Chief Compliance Officer or Global HCP Transparency Lead

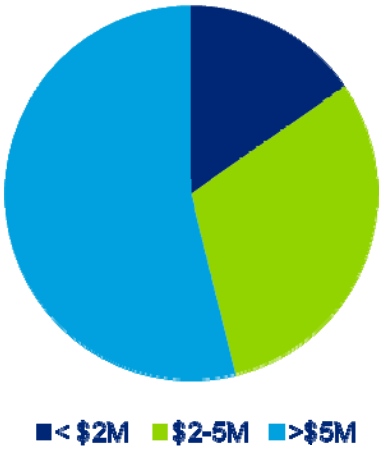
Manufacturer



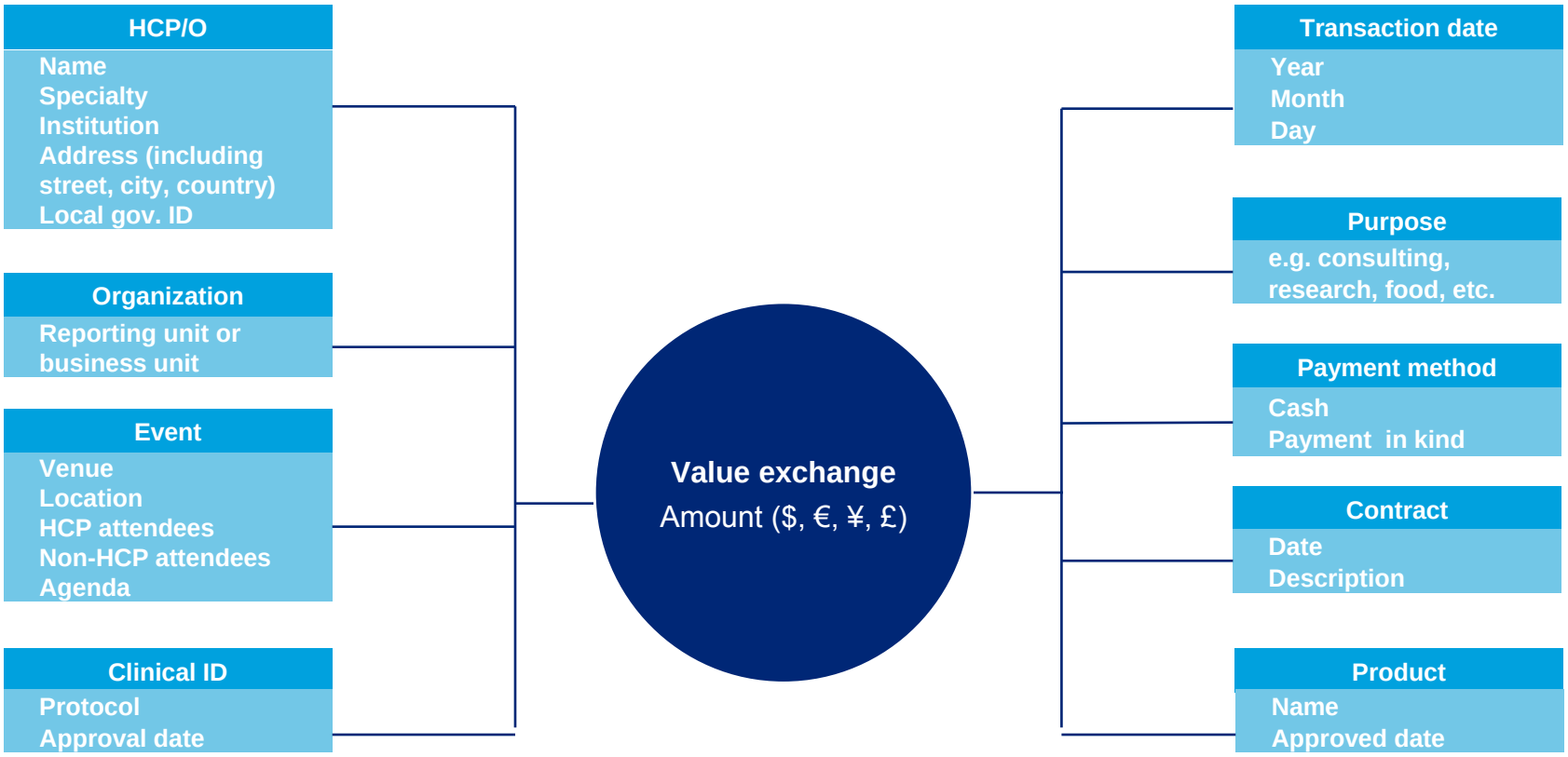
Headquarters



Size (2012 Revenue)

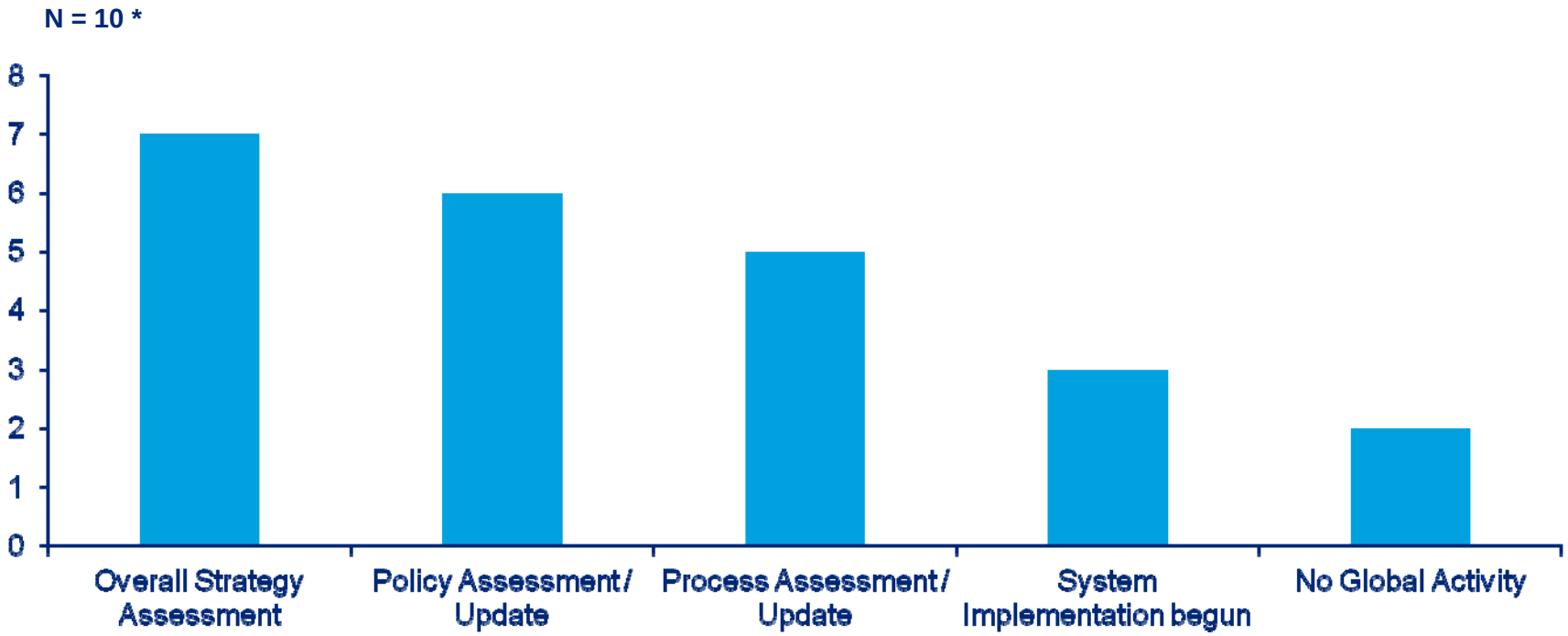


Global HCP transparency data attributes



All HCP Transparency Disclosure Regulations can be met using just 10 data attributes

Global HCP transparency projects initiated



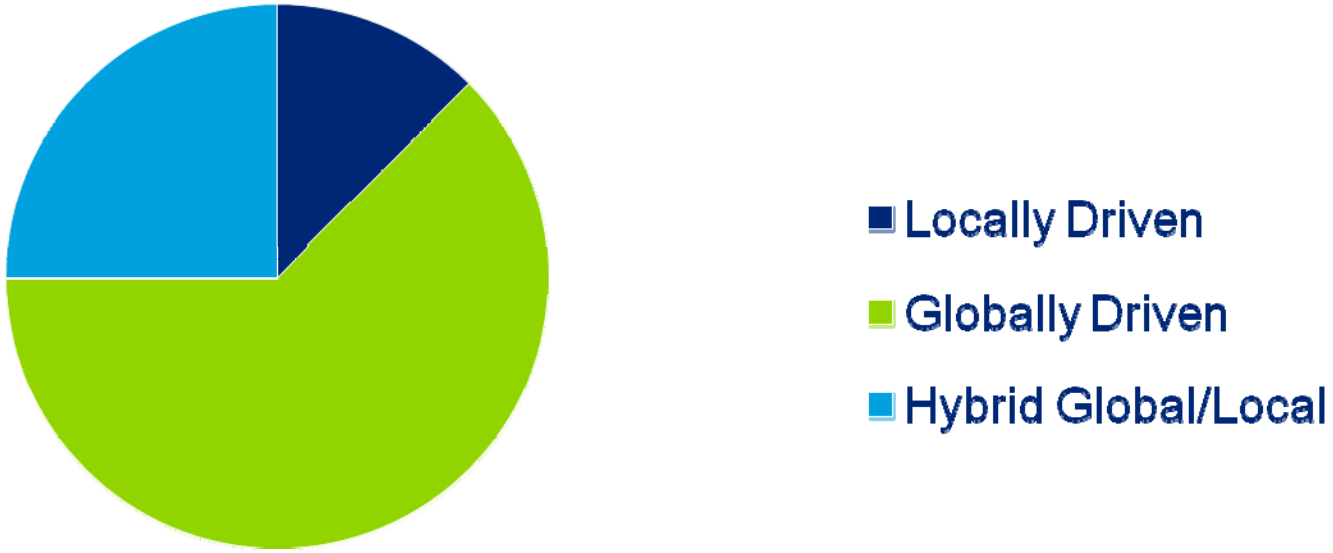
Question: What type and scope of project (if any) has your company initiated to address increasing global HCP/O transparency requirements? (Multiple responses allowed)

* 10 of 12 survey respondents answered this questions

Most companies surveyed have an Global HCP Transparency Assessment underway. Very few have started implementing systems

Global HCP transparency projects initiated

N = 8

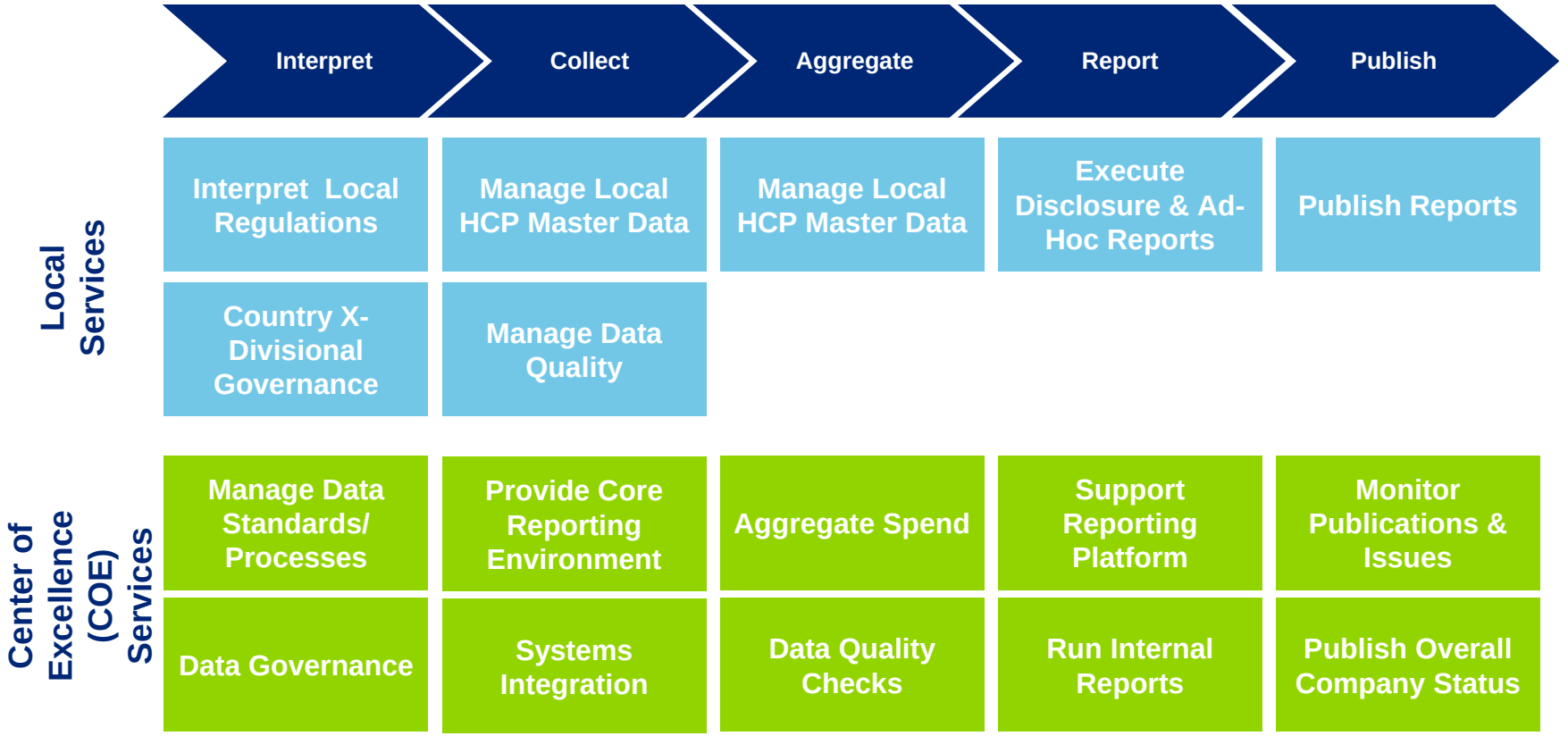


Question: Which of the following best describes your future vision for a solution, including process, policy, and systems, required to manage increasing Global HCP/O Transparency requirements?

Most companies surveyed that do have a global initiative underway report that the initiative is driven by a global team

Approach to global HCP transparency

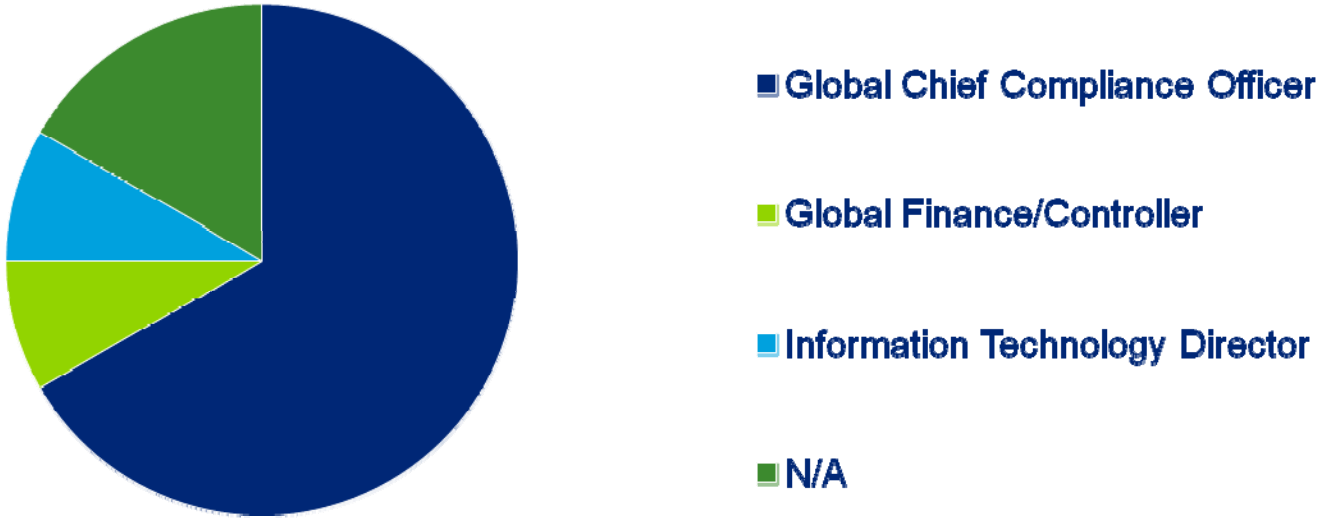
For Illustrative Purposes Only



Global HCP Transparency can be viewed as a set of services that can be standardized and used by the local countries/divisions

Leader of global HCP transparency program

N = 12



Question: Which is the title of the role who will most likely lead your efforts to better manage Global HCP/O Transparency issues?

N/A applies to respondents who do not have a global HCP Transparency project underway

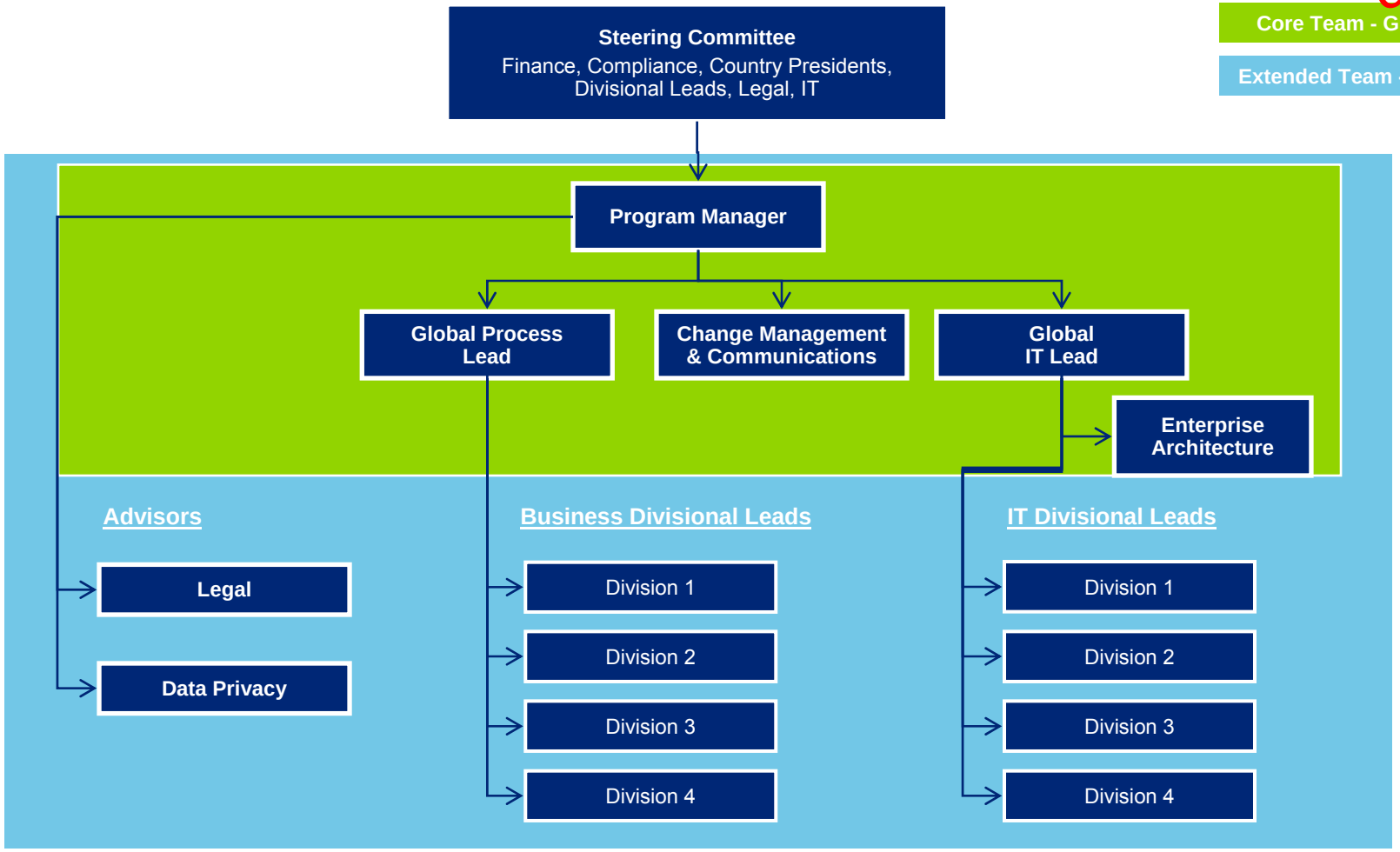
Most companies surveyed that do have a global initiative underway report that the Global Chief Compliance Officer is leading the effort

Global HCP transparency governance model

For Illustrative Purposes Only

Core Team - Global

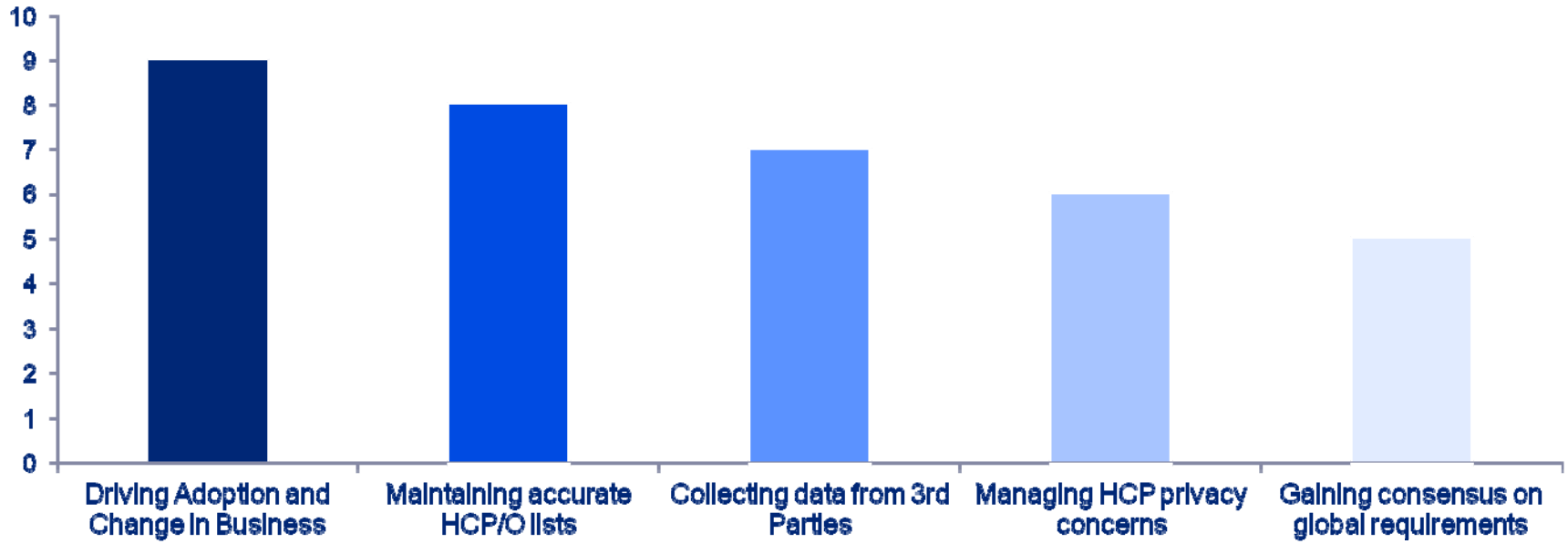
Extended Team - Local



Governance should include global and local representation

Challenges facing global HCP transparency programs

N = 11



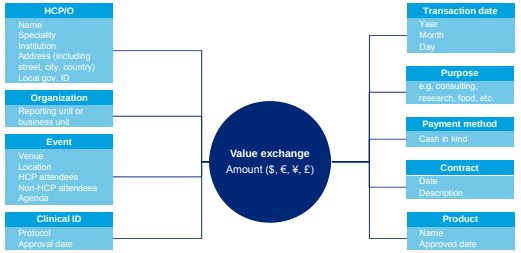
Question: Rank the following items for what you believe will be the biggest challenges to achieving the vision of a global program for HCP/O Transparency.

Survey participants asked to rank their top 4 challenges

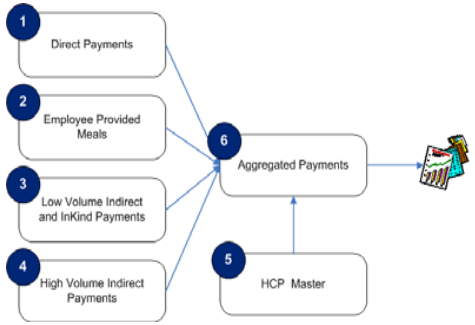
The top ranked challenge to those surveyed was driving adoption and change in the business.

Closing thoughts

Common data elements



Common enterprise sources



Many low volume sources

Center of Excellence which includes Core technology components that can be made available to many countries as a service

Industry Consortium which includes Core technology components that can be made available to many companies as a service

Commonality in data, systems and processes across countries leads to the conclusion that a standardized approach may likely reduce redundancies, improve data quality and reduce total overall costs

Global HCP transparency landscape

U.S.

Description of governing regulation or code(s)

•**Patient Protection and Affordable Care Act (PPACA) - The Physician Payments Sunshine Act:** Any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual) shall submit the information. Reporting of physician ownership or investment interests.

•Government Legislation enforced by **Centers for Medicare & Medicaid Services (CMS)**

Public disclosure

•**SEC. 1128G. Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.)** - Pursuant to the USSA, covered manufacturers will be required to report payments related to "any transfer of value, " value less than $10 unless the aggregate annual amount per covered recipient exceeds $100

Reportable information:

•Physician name
•Business address
•Physician specialty
•National provider ID
•Payment value
•Form of payment (e.g., cash, in-kind services)
•Payment date

Time frame

PPACA; Sunshine Act

Effective on 01 August 2013

Reporting to CMS by 31 March 2014

Covered activities

•Gifts
•Food
•Entertainment
•Travel
•Honoraria
•Research funding
•Education
•Research
•Profit distribution
•Charity contribution
•Consulting fees
•Faculty or speaker fees
•Investment interest
•Royalties
•License fees
•Speaking fees
•Dividends
•Stock or stock options

Source:
Patient Protection and Affordable Care Act (www.cms.gov)

Covered entities

•**Physician -** Doctor of medicine (MD) or osteopathy (DO), dentist, podiatrist, optometrist, chiropractor

•**Teaching Hospital —** Hospitals that receives federal funds to support an approved graduate medical education

•**Any applicable manufacturer or applicable group purchasing organization** - Includes drugs, devices, biologics or medical supply

Proposed penalties

Violation of PPAACA, Sunshine Act

•Failure to report — $1000 min and $10,000 max

•Knowing failure to report — $10,000 min and $100,000 max

•Max penalty not to exceed $1,000,000

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Mexico

Description of governing regulation or code(s)
•**CETIFARMA (CONSEJO DE ÉTICA Y TRANSPARENCIA DE LA INDUSTRIA FARMACÉUTICA) Codes of The Pharmaceutical Industry** — Guidelines for the interaction between physicians and the pharmaceutical industry both on a private and a public level
•Voluntary industry code
Others:
•International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

Transparency clause
•**Sec 4.9.5 Codes of the Pharmaceutical industry** — Companies will make available to the public information concerning the donations granted in order to promote transparency
•**Sec 3.1 Codes of the Pharmaceutical industry** — Pharmaceutical Industries, when required, must make available to CETIFARMA a list of the Patient Organization to which they provide financial or any other kind of support

Time frame
CETIFARMA
Effective since March 2012

Covered activities
•Donations and Grants
•Sponsorship

Covered entities
•Physicians
•Health institutions
•Patient organizations
•Sanitary authorities
•Pharmaceutical companies

Proposed penalties
Violation of code of Ethics, **CETIFARMA**
•A reprimand
•A financial penalty
•Temporary suspension of member's rights
•Permanent suspension or expulsion

Source:
Certifarma Codes of the Pharmaceutical Industry (http://www.amiif.org.mx)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Brazil

Description of governing regulation or code(s)
•**Interfarma's — Brazilian Research-Based Pharmaceutical Manufacturers Association Code of Conduct - R**eflects the industries commitment in contributing to the consolidation in Brazil of a pharmaceutical market conscious of their responsibilities towards patients, consumers, doctors and all healthcare professionals whom they are connected
•Voluntary industry code
Others:
•National Health Surveillance Agency (ANVISA)
•Brazilian Advertising Self-Regulation Code

Transparency clause
•**Sec-1.1.5 Intefarma-*Transparency in Relationship:*** Companies are not allowed to maintain veiled relationship with Healthcare Professionals, Related Healthcare Professionals or Institutions, Bodies, Associations or Companies connected with the Healthcare sector
•**Sec-3 Interfarma-*Transparency in Contract*:** The existence of an agreement between pharmaceutical company and healthcare professional must be in writing specifying the nature of the services to be provided and the criteria to remunerate these services
•**Sec 12 Intefarma-*Transparency in Donations*:** Contributions to Institutions, bodies, associations and companies of the healthcare sector

Time frame
Interfarma's
Effective since 01 July 2012

Covered activities
•Donations and contributions
•Hiring of professionals
•Contracting healthcare specialized services

Covered entities
•**Healthcare Professional** - medical, dental or pharmaceutical profession
•**Related Healthcare Professionals** – any person who can influence the prescription, dispensation, or recommendation of medicines
•**Institutions, Bodies, Associations and Healthcare Companies -** medical, pharmaceutical and patient representative classes, regulatory agencies

Proposed penalties
Violation of Interfarma
•R$ 2,200 — R$ 82,500 for minor infractions
•R$ 82,500 — R$ 220,000 for major infractions
•R$ 220,000— R$ 1,650,000 for severe infractions

Source:
Association of Pharmaceutical Research (http://www.interfarma.org.br/site2/index.php)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Argentina

Description of governing regulation or code(s)
•**Cámara Argentina de Especialidades Medicinales (CAEME) Code of Ethics - Issued by Pharmaceutical Industry Association of Argentina:** Governs interactions between pharmaceutical companies and healthcare professionals
•Voluntary Industry code
Others:
•IFPMA (International Federation of Pharmaceutical Manufacturers & Associations)

Transparency clause
•**Sec2.5 Code of Ethics — CAEME *Transparency of Promotion*:** Pharmaceutical companies must not involve in disguised promotional campaign. Clinical assessment controls, after sales experience programs and studies must be conducted with a primary educational and scientific purpose
•**Sec 7.5.4, Code of Ethics — CAEME *Entertainment*:** Members companies should not offer or fund stand-alone entertainment or other leisure or social activities. At events, entertainment of modest nature which is secondary to refreshments and/or meals is allowed.

Covered activities
•Promotional campaign
•Gifts
•Educational events
•Travel

Proposed penalties
•N/A

Time frame
CAEME
Effective since January 2007

Covered entities
•Healthcare professionals
•Pharmaceutical companies

Source:
CAEMA Code of Ethics
(http://www.caeme.org.ar/)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Europe

Description of governing regulation or code(s)

- **European Federation of Pharmaceutical Industries and Associations (EFPIA) — HCP CODE —** Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals, seeks to ensure that pharmaceutical companies conduct such promotion and interaction in a truthful manner, avoiding deceptive practices and potential conflicts of interest
- **EFPIA Patient Organisation (PO) Code —** Code of practice on relationships between the pharmaceutical industry and patient organizations
- Voluntary industry code

Transparency clause

EFPIA — HCP code

- **HCP Article 11 —** publicly disclose donations, grants or benefits in kind that support healthcare or research
- **HCP ARTICLE 15 —** Non-Interventional Studies Of Marketed Medicines — companies are encouraged to publicly disclose the summary details and results

EFPIA — Patient Organization (PO) code

- **PO Article 5 —** Transparency — publicly disclose list of patient organizations, description of the nature of the support, and monetary value of financial support. Also includes Contracted Services from the PO

Information may be provided on a national or European level, and should be updated at least once a year

Time frame

EFPIA — HCP code

Effective since 01 January 2012

EFPIA — PO code

Approved 2007

Covered activities

- Transparency of Promotion
- Events and Hospitality
- Gifts
- Donations and Grants
- Fees for service
- Sponsorship
- Use of consultants
- Non-interventional studies of marketed medicine
- Medical samples
- Contracted service

Covered entities

- **Healthcare professionals**
- **Patient organizations —** Not-for-profit organizations (including the umbrella organizations to which they belong)
- **3rd parties —** Member companies shall be responsible even if they commission other parties to design, implement or engage in activities on their behalves

Proposed penalties

Violation of EFPIA — HCP code

- Immediate cessation of the offending activity and a signed undertaking by the company to prevent recurrence
- Suggested combination of publication and fines are generally considered to be the most effective sanctions

Source:

European Federation of Pharmaceutical Industries and Associations HCP Code (http://www.efpia.eu/codes-practice)

** Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Norway

Description of governing regulation or code(s)
•**LMI (Legemiddelindustrien) Code of Practice — Rules of marketing medicinal products:** Implemented on 15 November 1994 by the General Meeting of the Association of the Pharmaceutical Industry in Norway
•Voluntary industry code
Others:
•Advertising and promotion of pharmaceutical products including interactions with healthcare professionals is regulated by:
–*Norwegian Act on Medicinal Products* of December 1992, Chapter VII
–*Norwegian Regulation on Medicinal Products* of December 1999, Chapter XIII
–*Norwegian Marketing Control Act* of June 1972

Transparency clause
Professional gifts shall have a value that does not exceed NOK 1000

•**Section 11 LMI:** Donations to institutions or organizations for the purpose of supporting medical research or treatment
•**Section 14 LMI:** Contracts with health professionals concerning assignments/provision of services
•**Section 4.5 LMI:** The pharmaceutical company must ensure transparency concerning agreements between the company and medical expertise

Time frame
LMI: Code of Practice
Effective since 14 March 2011

Covered activities
•Conferences, Symposia, Meetings
•Events
•Hospitality
•Travel
•Accompanying persons prohibited
•Social activities, and prohibition of certain destinations
•Gifts and benefits
•Use of Consultant, Consultation fees
•Scholarship
•Samples

Covered entities
•**Healthcare professionals:** Includes physicians, pharmacist, nurses
•**Pharmaceutical companies**

Proposed penalties
Violation of LMI
•N/A

Source:
LMI Code of Conduct
(http://www.efpia.eu/)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Sweden

Description of governing regulation or code(s)
•**Swedish Association of the Pharmaceutical Industry (LIF):** issued the *Ethical Rules for the Pharmaceutical Industry* which provide guidelines to the pharmaceutical industry on their interactions with healthcare professionals.
•Voluntary industry code
Others:
•The Medicinal Products Act Regulation (LVFS 2009:6) - issued by the Swedish Medical Products Agency

Transparency clause
•**Section 3, Article 43.1; Ethical Rules LIF:** The cooperation between pharmaceutical companies and organizations should be regulated in written agreements.
•**Section 3, Article 43.3; Ethical Rules LIF:** Contracts and agreements between organizations and pharmaceutical companies should also be kept available to third parties, whether ongoing, concluded or regarding future projects.
•**Section 3, Article 38; Ethical Rules LIF:** Support or sponsorship from pharmaceutical companies of an activity/conference are encouraged to publicly announce.

Time frame
LIF
Effective since 01 September 2012

Covered activities
•Service Fees
•Travel and Accommodations
•Conferences
•Meeting and Events
•Meals
•Gifts or Financial Benefits
•Sponsorship

Covered entities
•**Healthcare professionals:** physicians, dentists, veterinarians, senior pharmacists and pharmacists, nurses, opticians and dental hygienists
•**Pharmaceutical companies:** Refers to medicine marketer, importer, marketing authorization holder or other entrepreneur engaged in pharmaceutical marketing
•**Patient association:** NGOs (organizations of public utility), their local and regional associations and central organizations

Proposed penalties
Violations of LIF
•Prison for up to two years
•In the event of a serious offence, the party will be sentenced to imprisonment for a minimum of 6 months and a maximum of 6 years

Source:
Ethical Rules for the Pharmaceutical Industry (http://www.lif.se/)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Finland

Description of governing regulation or code(s)
•**Pharma Industry Finland (PIF) Code of Ethics:** Generally accepted code of conduct. All major players in the pharmaceutical industry (in Finland) who are members comply with the PIF Code
•Voluntary industry code
Others:
•FIMEA Finnish Medicines Agency
•*Medicines Act (395/1987, as amended)*
•*Medicines Decree (693/1987, as amended)*
•*Consumer Protection Act (38/1987, as amended)*
•*Unfair Business Practices (1061/1978, as amended)*

Transparency clause
•**Section 4 PIF Code of Ethics:** Pharmaceutical company must ensure that its sponsorship to the patient organization is public by nature, and support is clearly disclosed.
•**Section 2 PIF Code of Ethics:** Pharmaceutical companies are encouraged to publish the information on donations, grants and benefits in kind to institutes, organizations or associations.
•**Section 2 PIF Code of Ethics:** Pharmaceutical companies must include a term whereby the consultant is liable to disclose his/her consultation relationship to the company whenever he/she writes or speaks in public about the issue constituting the object of the contract or otherwise related to the company.

Time frame
Pharma Industry Finland
Effective since 01 July 2008

Covered activities
•Use of Consultants
•Hospitality
•Events, Meeting and Trainings
•Gifts
•Donations and Grants
•Non Interventional Studies
•Free samples of Medicine

Covered entities
•Healthcare Professionals
•Pharmaceutical Companies
•Patient Association

Proposed penalties
Violation of PIF Code of Ethics:
•Minimum of EUR 1,000 to a maximum of EUR 50,000

Source:
Pharma Industry Finland Code of Ethics (http://www.pif.fi/)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

United Kingdom

Description of governing regulation or code(s)

•**The Association of the British Pharmaceutical Association (ABPI) Code of Practice for the Pharmaceutical Industry, 2012 second edition:** Aims to ensure that the promotion of medicines to health professionals and to administrative staff is carried out within a robust framework to support high quality patient care

•Voluntary industry code

Others:

•UK Bribery Act (new act — 2010): Requires all companies to implement adequate procedures to prevent bribery globally

Public disclosure

•**Clause 18.6 ABPI** — Donations, grants and benefits in-kind

•**Clause 19.4 ABPI** — Total amount paid per year, sponsorship fees, accommodation and travel in relation to attendance at meetings, speaker fees, market research

•**Clause 20.2, 20.3 and 20.4 ABPI** - Consultancy fees and expenses for services such as chairing and speaking at meetings, assistance with training and participation in advisory boards etc., as well as market research (20.3)

•**Clause 23.7 ABPI** — List of patient organizations, including the monetary value of support. Financial details of sponsorship of UK health professionals and appropriate administrative staff in relation to attendance at meetings organized by third parties

Time frame

ABPI

Effective since 2012

Disclosure by 2013

Covered activities

•Journal and direct mail advertising

•Activities of pharmaceutical sales representatives

•Samples of medicines

•Provision of inducements (either in money or in kind)

•Details of each grant or donation

•Provision of hospitality

•Fees paid to consultants

•Sponsorship of promotional meetings

•Sponsorship of scientific meetings (including payment of travelling and accommodation expenses) and all other forms of sales promotion (including exhibitions and the Internet)

Source:

ABPI Code of Practice for Pharmaceutical Industry, 2012 second edition

(http://www.pmcpa.org.uk/Pages/default.aspx)

Covered entities

Health professionals – Doctors, dentists, pharmacists , nurses and administrative staff

Organizations - Associations and patient organizations, hospitals/hospital trusts, group Practices

Pharmaceutical companies

Proposed penalties

Violation of ABPI

•Cessation of conduct

•Audit of company's procedures

•Public reprimand

•Recovery of material

•Issuing corrective statement

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Ireland

Description of governing regulation or code(s)
Irish Pharmaceutical Health Association (IPHA) - Code of Marketing Practice for the Pharmaceutical Industry, Edition 7.5 — Implements high standards of conduct in the marketing of medicinal products to healthcare professionals
Voluntary code
Others:
•(Control of Advertising) Regulations 2007 (S.I. 541 of 2007)

Transparency clause
•**Sec-3 IPHA Code of Marketing Practice for the Pharmaceutical Industry** — Each company must make publicly available a list of patient associations to which it provides financial support:
- Description of the nature of the support
- Monetary value of financial support
- Total amount paid per patient organization over the reporting period
- Any non-monetary benefit that the patient association receives

•**Sec 15 IPHA Code of Marketing Practice for the Pharmaceutical Industry** — Companies to make available, publicly, information about donations, grants or sponsorship

The information must be provided by companies for the first time by the end of the first quarter of 2013 (covering activities commenced as of, or ongoing on, 01 January 2012).

To be published on a national and on European level and is to be updated at least once a year

Time frame
IPHA Code
Effective since 01 January 2012

Covered activities
•Donations
•Grants
•Gifts
•Samples
•Education and research
•Sponsorship
•Hospitality, meetings, congresses conferences, and symposia
•Clinical trials
•Non interventional studies

Covered entities
•**Healthcare professional —** registered medical practitioners, registered dentists, registered pharmacists, and registered nurses
•**Pharmaceutical industry**
•**Patient associations —** patient and healthcare advocacy groups which are not disease specific

Proposed penalties
Violation of Code of Marketing Practice for the Pharmaceutical Industry, IPHA
•N/A
•Reputational harm

Source:
Irish Pharmaceutical Health Association (http://www.ipha.ie/)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Netherlands

Description of governing regulation or code(s)

•**NEFARMA (the Dutch industry association of the research-based pharmaceutical companies) Code of Conduct for the Disclosure of Financial Relations:** Applies to pharmaceutical advertising and the code of conduct for sponsoring; financial relation in terms of direct or indirect financial, or non-financial support from a license holder to a healthcare professional (HCP) registered and/or practicing in the Netherlands

•Voluntary industry code

Public disclosure

NEFARMA Code of Conduct

To disclose within three months if the total amount is beyond EUR 500 per year

•**Article 1a Code of Conduct (Financial Relations)-** Service agreements between license holders and (partnerships of) healthcare professional

•**Article 1b Code of Conduct (Financial Relations) -** Sponsoring agreements between license holders and partnerships of HCPs and/or to a healthcare institution in which the HCP participates or is employed

•**Article 2a Code of Conduct (Disclosure)** - Personal details of the HCP that has provided the service and the total amount of fees paid to the HCP

•**Article 2b Code of Conduct (Disclosure) -** Details of the partnership of HCP's and/or to a healthcare institution in which the HCP participates or is employed by and the total paid amount

Time frame

NEFARMA

Effective since 01 January 2012

Disclosure by April 2013

Covered activities

•Personal Details**:** Name, field of expertise and professional address of the HCP

•Total amount of fees paid to the HCP

•Service agreement between license holder and HCP which includes, consulting, advisory, speaker, non-speaker, research

•Sponsoring agreement between license holders and partnerships of HCPs

Source:

NEFAMRA Code of Conduct for the Disclosure of Financial Relations (http://www.nefarma.nl/)

Covered entities

•**Healthcare professionals —** Medical, dental, pharmacy or nursing professionals, any person who may prescribe, supply or administer a medicine

•**Healthcare institutions -** Healthcare institution in which the HCP participates or is employed.

•**Pharmaceutical companies**

Proposed penalties

Violation of NEFARMA

•Under the Medicines Act, the Minister of Health can impose fines up to EUR 450,000 (estimated at US$643,000) for infringement of the hospitality restrictions.

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Belgium

Description of governing regulation or code(s)
•**Pharma.be's Code of Deontology:** supplements all legal and regulatory provisions on the subject of promoting and providing information on medicinal products for human use
•Voluntary industry code
Others:
•Mdeon (self-regulating body created jointly by the national association of doctors and pharmacists, the pharma and medical device industries)
•The Medicines Law of 25 March 1964

Transparency

Article 49 — Pharma.be's Code of Deontology
Disclose list of patient organizations to which it provided support and include the following:
- Nature of the support provided
- Amounts of money involved
- Non-financial benefit received to be described clearly

Time frame

Pharma.be's Code of Deontology
Effective since March 2012

Covered activities

•Nature of the services provided by pharmaceutical company to patient organizations

Covered entities

•Health professionals
•Patient organizations
•Pharmaceutical companies

Proposed penalties

•N/A

Source:
Pharma.be Code of Deontology (http://www.efpia.eu/)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Germany

Description of governing regulation or code(s)
•**FSA (Freiwillige Selbstkontrolle für die Arzneimittelindustriee.V — FSA) Code of Conduct:** Principle applies that pharmaceuticals are to be adequately advertised, avoiding unfair practices and conflicts with healthcare professionals in relation to professional ethics
•Voluntary industry code
Others:
•HWG (Heilmittelwerbegesetz):*German Advertising in the Health Care System Act*
•AMG (Arzneimittelgesetz): German Drug Act
•UWG (Gesetz gegen den unlauteren Wettbewerb): General provisions of the Act Against Unfair Competition
•StGB (Strafgesetzbuch): German Penal Code

Transparency clause
•**Sec 25 FSA —** The companies must publish the granting of donations or other unilateral monetary or benefits in kind with a value of more than € 10,000 per benefit recipient/year

Time frame
FSA
Effective since 1 December 2012

Covered activities
•Lectures, Consulting, Advisory Fee
•Meetings
•Training Events
•Hospitality
•Travel Expenses
•Gifts
•Non Interventional Studies
•Clinical Trials

Covered entities
•**Healthcare professional:** Physicians and pharmacists, any member of the medical, dental, pharmacy or other nursing professions. Person whose professional activities may prescribe or apply or lawfully trade in medicinal products for human use.
•**Pharmaceutical manufacturers**
•**Patient association**

Proposed penalties
Violation of FSA code
•Warning letter
•Fines (not defined)

Source:
FSA Code of Conduct (http://www.fsarzneimittelindustrie.de/verhaltenskodex/patientenorganisationen/)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Poland

Description of governing regulation or code(s)
•**INFARMA: (self-regulated body of the Employers Union of Innovative Pharmaceutical Companies [INFARMA]) -** The 'Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organizations' adopted by INFARMA)
•Voluntary industry code
Others:
•The Pharmaceutical Law of September 6, 2001
•Law on healthcare services financed from public funds of August 27, 2004
•Minister of Health of November 21, 2008

Transparency clause
•**Article 30 INFARMA:** Conducting non-interventional studies or trials/studies shall be prohibited in the event they represent a form of concealed advertising aiming at increasing the number of issued prescriptions
•**Article 47 INFARMA:** Signatory of the Code shall make publicly available a list of patient organizations to which it provides financial support or substantial in kind or other non-financial support
•**Article 47 INFARMA:** In the case of substantial non-financial support, the description shall describe the benefit provided to a given patient organization

Time frame
INFARMA
Effective since 07 February 2012

Covered activities
•Venue of Meetings
•Hospitality
•Non Interventional trials
•Gifts
•Contributions to Healthcare
•Sponsorship
•Employing Consultant

Covered entities
•**Healthcare professionals:** The professionals entitled to prescribe or dispense medicines include physicians, dentists, nurses and dentist
•**Pharmaceutical companies**
•**Patient association:** refers to entities associating patients or cares representing or supporting patients or organizations associating such entity

Proposed penalties
Violation of INFARMA
•N/A
•Reputational harm.
•Benefits to be declared above PLN 100

Source:
Infarma Code of Conduct
(http://www.efpia.eu/)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Hungary

Description of governing regulation or code(s)
Code of Ethics For Pharmaceutical Marketing Communications (Hungarian National Code) — The Hungarian Pharmaceutical Manufacturers Association, Association of Innovative Pharmaceutical Manufacturers and Communication Ethics Committee run by the Associations (KEB):ethical pharmaceutical marketing communication
Voluntary industry code
Others:
•Act CLXXXV of 2010 on Media Services and on the Mass Media
•Act XCVIII of 2006 on the General Provisions Relating to the Reliable and Economically Feasible Supply and distribution of Medicinal Products and Medical Aids

Transparency clause
•**Sec-11.2 Hungarian International Code** — Information regarding donation and grants to institutions, organizations or associations comprised of Healthcare Professionals to be made publicly available
•**Sec-11.4 Hungarian International Code** — No donation or grant to be given to Healthcare Professionals privately
•**Sec-18.9 Hungarian International Code** — Companies must make publicly available the list of Patient Organizations to which they provide monetary support and/or significant non-monetary support:
  – Value of the monetary support
  – Description of monetary support
  – Any non financial benefits or support

Information to be published on national or on European level to be updated at least once a year

Time frame
Hungarian International Code
Current amended code became effective 01 March 2012

Covered Activities
•Donation
•Grants
•Gifts and inducements
•Programs, events or get-togethers sponsored by companies for healthcare professionals
•Sponsorship
•Clinical trials
•Non interventional studies

Covered entities
•**Healthcare professional —** Healthcare personnel (doctor, pharmacist, healthcare assistant, member of health service provider staff or any other specialist) qualified to recommend, prescribe, procure, sell, supply or administer medicinal products
•**Pharmaceutical industry**
•**Patient organization —** Non-profit organizations consisting mainly of patients and their carers (including umbrella organizations that these organizations are member of)

Proposed penalties
Violation of Hungarian International Code
•N/A
•Reputational harm

Source:
Code of Ethics for Pharmaceutical Marketing Communications
(http://www.efpia.eu/)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Austria

Description of governing regulation or code(s)
•**Austrian Pharmaceutical Industries Association (Pharmig) Industry Code of Conduct ('Code 2009'):** Enables the pharmaceutical industry to meet its responsibility in healthcare in a professional manner while maintaining the high ethical standards
•Voluntary industry code
Others:
•The Physician's Code of Conduct ('Ärztlicher Verhaltenskodex')
•Medicinal Products Act (MPA)

Transparency clause

•**Sec 8a.4.1, Pharmig** — Pharmaceutical companies shall detail on their publicly accessible internet homepage all the patient organizations they support. Publication shall contain information about the nature and scope as well as a description of the support involved.
•**Sec 8a.4.2, Pharmig** — Pharmaceutical companies shall ensure that contracts/ written agreements disclose to the public the relevant support provided by patient organizations' transparently at all times and clearly from the outset.

Time frame

Pharmig
Effective since 01 July 2007, and amended on 01 July 2009

Covered activities

•Scope of interaction between pharmaceutical companies and patient organizations
•Symposia, congresses, workshops, lectures, small-scale events/meetings between, patients' organizations, continuing education

Covered entities

•**Applicable persons as defined by § 59 (3 and 4) MPA**
  – Physicians
  – Dentists, veterinary surgeons, denturists, midwives, members of the nursing profession
  – Medical laboratory services and paramedic services as well as the legal entities of hospitals without an in-house hospital
  – Pharmacy and any other medical facilities, provided they require medicinal products to fulfill their tasks
•**Patient organization**
•**Pharmaceutical companies**

Proposed penalties

Violation of Code of Conduct, Pharmig
•Penalty of not less than EUR 5,000 up to a maximum of EUR 100,000
•The penalty range is increased to EUR 200,000.00 if the company concerned has committed 3 violations of Article 7 or Article 9 of the Pharmig Code of Conduct within 24 months

Source:
Pharmig Industry Code of Conduct (http://www.pharmig.at/DE/Homepage.aspx)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Slovakia

Description of governing regulation or code(s)
•**National Centre for Health Information (NCHI) Code of Ethics of the Pharmaceutical Industry in Slovakia (revised 12th edition):** This Code regulates the promotion of medicinal products for human use subject to medical prescription to healthcare professionals, as well as promotional activities towards healthcare professionals
•**New Regulation of Drugs Policy, 2011 Act no. 362/2011 Coll. on Drugs and Medical Devices**
•Government Legislation enforced by **Ministry of Health** (MOH)
Others:
•Slovak Association of Research□Based Pharmaceutical companies (SAFS)

Public disclosure
•**Sec 10.4 NCHI Code of Ethics** — The companies must disclose on its website the list of patient organizations receiving the company's financial support and/or significant indirect/nonfinancial support.
•Within 30 days following completed quarter HCP or HC provider must inform (MOH) on:
- Amount of monetary and non□monetary income received
- Name and surname or commercial name of the payer
- Name and surname of the health worker
- Address of the health□care facility
- Purpose of income provision pursuant to the first point

•**Act no. 362/2011 Coll.:** Pharmaceutical company must submit value of advertising and marketing expense and non monetary benefits provided to HCP
•Reports must be sent annually to MOH by 31 Jan

Time frame
Code of Ethics
Effective since February 2012
New Regulation of Drugs Policy, 2011 Act no. 362/2011
Effective since 01 December 2011

Covered entities

•**Healthcare professionals**
•**Patient organizations**- non-profit entities composed mainly of patients and/or healthcare providers
•**Pharmaceutical company —** Any legal entity or a third party engaged to provide financial funds, or involved in activities with patient organizations and having its registered office in the Slovak Republic or in Europe

Covered activities

•Relations with Patient Organization
•Drug advertising and promotion
•Scientific and Professional Events
•Research
•Non interventional Clinical Trials

Proposed penalties

Violation of NCHI Code of Ethics
•In case of severe intentional/repeated breaches of code, penalties will be imposed. Values to be determined.
Violation of Act no. 362/2011 Coll.
•Fine up to 25, 000 Euros

Source:
Slovak Association of Research-Based Pharmaceutical Companies Code of Ethics (http://www.safs.sk/En/index_en.html)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

France

Description of governing regulation or code(s)

•**French Code of Public Health ("Code de la santé publique" or 'CSP')** is known as "Law No. 2011-2012 of 29 December 2011 on the Strengthening of Health Protection for Medicinal and Health Products" ("loi relative au renforcement de la sécurité sanitaire du médicament et des produits de santé"), referred to as the "French Sunshine Act" requires companies to disclose any advantage in kind or in payment provided to persons/organizations.

•Government Legislation enforced by **Ministry of Health (MOH) France.**

Public disclosure

Threshold of benefits to be EUR 10, including taxes

•**Includes contracts** — R&D, consultancy, advisory, speaker service

- name and other information of HCP
- date of contract signed
- purpose and subject of contract

•**Hospitality convention** — HCPs at scientific or medical events registration fees, travel costs, meals and accommodation expenses

•**Benefits** — For payments, gifts i.e. storage stick, mouse mats and other benefits of one euro or more provided directly or indirectly to HCPs

- Identity of recipient of benefit
- Cumulative amount of benefit awarded

To disclose within 15 days of signing contract or within 15 days after payment is made

To be updated each year

Time frame

French Sunshine Act effective in December 2011

Proposed Decree (First Draft) issued in February 2012

Proposed Decree (Second Draft) – pending

Disclosure by early in 2013

Covered activities

•Gifts
•Lunch
•Registration fees
•Travel costs
•Meals and accommodation expenses
•Advantages in kind or in cash, direct or indirect
•Clinical trials
•Observation studies
•Advisory grants
•Speaker fees

Covered entities

•**Healthcare professionals** — HCP whose practice is regulated by the FCPH

•**Association of HCP/Students of medicine** and other healthcare related studies and associations

•**Healthcare establishments** — HCP associations, public hospitals or private clinics, patient associations, research foundations

•**Life Sciences companies** — Manufacturers of medicinal products, devices, and cosmetics

•**Legal entities** — Providing or participating in the initial training of healthcare professionals

Proposed penalties

Violation of French Sunshine Act

•EUR 45,000 fine in case of deliberate omission of disclosure for an *individual,* EUR 225,000 for a *company*

•Fine up to EUR 30,000 for a person under the duty to disclose potential conflicts of interest but knowingly fails to issue or update, gives false information

Source:
French Sunshine Act and Disclosure Rules (http://www.leem.org)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Spain

Description of governing regulation or code(s)

•**Farmindustria (National Business Association of the Pharmaceutical Industry) and Spanish Federation of Healthcare Technology Companies (FENIN) new version approved on 26 October 2010:** Transparency regimes are imposed by the industry associations of both the medicinal products sector

•Voluntary industry code

Others:

•European Federation of Pharmaceutical Industries and Associations (EFPIA) Code

Public disclosure

Threshold of gifts higher than value >10 Euros is not permissible

•**Sec 11, Farmaindustria —** Hospitality, meetings, conferences and events of a scientific and/or promotional nature must be communicated to the Surveillance Unit of Farmaindustria

•Notification must include:

- Name and address of company
- Nature of its participation
- Number of HCP invited and participants
- Place and dates to be held
- Scientific program specifying number of hours
- Social program and parallel activities

•**Sec 14.3 Farmaindustria** — Market research studies: sponsoring or financing from pharmaceutical company, paid participation of less than 20 HCPs

Time frame

Farmaindustria

Effective since 26 October 2010

Covered activities

•Hospitality

•Meetings and events of a scientific and/or promotional nature

•Travel

•Market research studies

•Gifts

Source:

Spanish Code of Practice for the Promotion of Medicines and Interactions with Healthcare Professionals (http://www.fenin.es/en/index.php)

Covered entities

•**Healthcare professionals** — Person who, in the practice of his/her professional activity, can carry out or determine the activities of prescribing, buying, distributing, dispensing or administrating a medicine

•**Company -** Legal entity**,** whether the company headquarters, control company, marketing company, subsidiary, or any other form of legal entity organizing or sponsoring promotional activities in Europe

Proposed penalties

Violation of FARMAINDUSTRIA

•Minor offences: EUR 6,000 - 120,000

•Serious offences: EUR 120,000 - 240,000

•Significant offences: EUR 240,001 - 360,000

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Italy

Description of governing regulation or code(s)

•**Farmindustria (Association of Pharmaceutical Companies) - Code of Professional Conduct -** Sets out to regulate relations not only between companies, but also their relations with the scientific and health sectors.

•Voluntary industry code

Others:

•Agenzia Italiana del Farmaco (AIFA) - Italian Medicines Agency: National authority responsible for drug regulation in Italy

Transparency clause

•**Sec 4.1, Farmaindustria:** A written contract must be stipulated between the physician and the pharmaceutical company specifying the nature of the service offered. The need for the service in question must be clearly identified and stated

•**Section 4.6, Farmindustria** Companies must make publicly a list of Patient Associations to which it provides financial support, referred to the previous year, including the monetary value of financial support for each association

Time frame

Farmindustria

Effective since 23 October 2012

Covered activities

•Consulting fees
•Scholarships
•Clinical trials
•Hospitality
•Conference Events: Congresses, Meetings
•Web based Trainings
•Satellite Symposia
•Samples

Covered entities

•Healthcare professionals
•Pharmaceutical companies
•Patient association

Proposed penalties

Violation of Farmindustria

•Sanction up to EUR 200,000

Source:

Farmindustria Code of Professional Conduct (http://www.farmindustria.it/Farmindustria/html/index.asp)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Czech Republic

Description of governing regulation or code(s)
•**Association of Innovative Pharmaceutical Industry (AIFP) Code):** Covers promotional activity and communication directed at any person who in the course of his or her professional activities prescribe or supply a Medicinal Product
•Voluntary code
Others:
•Article 2 of the Act No. 79/1997 Coll

Public disclosure
Sec 7.1 AIFP Code-Travel and Meetings - Sponsors must publicly disclose purpose of meetings and proceedings

Sec 8 AIFP Code-Sponsorships - Members should disclose support to professional activities, by either financial or other means

Time frame
AIFP
Established in 1993
Effective since 13 September 2012

Covered activities
•Hospitality
•Gifts and Inducement
•Medical Educational Materials
•Fees paid to Consultant, services, speaker fee, advisory and market research
•Travel and Meetings
•Sponsorship
•Research

Covered entities
•**Healthcare professional -** Medical, dental, pharmacy or nursing professionals, any person who may prescribe, purchase, supply or administer a medicine, or provide healthcare services
•**Pharmaceutical Industry -** Companies involved in Research and Development of new medicines, production and distribution of generic pharmaceuticals
•**Authorities –** Companies that promotes the prescription, supply, sale, administration or consumption of its medicinal product

Proposed penalties
Violation of AIFP code
•Minor breach maximum of 200,000 CZK
•Major breach maximum of 500,000 CZK, Repeated major breach, maximum of 1,000,000 CZK (within 24 months)

Source:
Association of Innovative Pharmaceutical Industry Code (http://www.aifp.cz/cz/index.php)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Turkey

Description of governing regulation or code(s)
•**Association of Research-Based Pharmaceutical Companies (AIFD):** Prime body for laying out '*Code of Practice' for pharmaceutical companies.* Main regulation governing the advertising of medicinal products is the 'Regulation of Promotion Activities of Medicinal Products for Human use
•Government Legislation enforced by **Ministry of Health (MOH)**
Others:
•Regulation on Ethics Rules for Public Servants and its Application
•TTB (Turkish Medical Association)

Public disclosure

•**21.7.1, AIFD** — Each company must make publicly available a list of patient organizations to which it provides financial support and/or a significant direct or indirect non-financial support
  – Includes monetary value
  – Amount of invoiced costs
  – Non-monetary support received by the patient association.

21.7.3-, AIFD — Pharmaceutical companies should publish the list of patient organizations to which it provides significant service under contract
  – Nature and dimension of service provided
  – Importance for the association
  – Publish the total amount

Time frame

AIFD
Effective since 01 July 2012

Covered entities

•**Healthcare professionals** - Physicians, dentists and pharmacists, assistant healthcare personnel and healthcare personnel with regard to the administration of products to patients
•**Pharmaceutical Industry**
•**Patient Organizations**

Covered activities

•Gifts and Inducements,
•Donations
•Scientific and Educational Meetings and Hospitality
•Interactions with Consultants
•honorarium
•Non Interventional Studies
•Clinical Trials
•Samples

Proposed penalties

Violation of AIFD
AIFD Board of Directors and the General Assembly shall apply the following sanctions:
•Concern Letter
•Admonition
•Warning
•Condemnation
•Strong Condemnation
•Temporary Suspension from Association Membership
•Expulsion from the Association

Source:
Association of Research-Based Pharmaceutical Companies (http://www.aifd.org.tr/en/anasayfa.aspx)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Russia

Description of governing regulation or code(s)

•**Federal Law #323 "On the Foundations of Healthcare for Russian Citizens" (the "Law"):** Regulates the interaction between healthcare and pharmaceutical professionals and production or distribution of drugs and medical equipment and instruments
•Government Legislation enforced by **Ministry of Health (MOH) of the Russian Federation**
•**Russian Civil Code**
•**Russian Code of Marketing Practices of the Association of International Pharmaceuticals Manufacturers ("AIPM") —** not an Act, Code provides for regulations and restrictions of the interaction of pharmaceutical industry with health care professionals
- Voluntary industry Code

Transparency clause

•**Article 74 — Federal Law #323** — Prohibits healthcare professionals and pharmacists from:
  – accepting gifts, cash bonuses, paid entertainment, vacations travel, participating in entertainment that is paid for by organizations that produce or distribute medicines or medical appliances/equipment
•**Sec 575 of the Russian Civil Code** — Gifts should not exceed the value of 3,000 Rubles (70 Euros)
•**Sec 6.3.5, AIPM** — Pharmaceutical company should explicitly disclose the fact and nature of its cooperation with a patient organization on its website

Time frame

Federal Law #323
Effective since 23 November 2011 except for Articles 74 and 75 which became effective as of 01January 2012
AIPM
Effective since 01 January 2013

Covered activities

•Any relationship with Patient organization, health care professionals
•Gifts, cash bonuses
•Paid entertainment
•Vacations or travel
•Donations
•Sample medicines
•Education programs
•Clinical trials

Covered entities

•**Pharmaceutical industry:** Organizations that produce or distribute medicines or medical appliances/equipment
•**Healthcare professionals —** doctors and other medical professionals, heads of medical organizations, pharmaceutical professionals (including pharmacists), heads of pharmacy organizations, and other specialists whose professional activity is concerned with pharmaceutical products

Proposed penalties

Violation of AIPM Code-
•Financial fine in an amount not to exceed the current AIPM annual membership fee
•Expulsion from the AIPM
Violation of Federal Law #323:
•Liability and pay a penalty that shall not exceed fifty minimum monthly salaries for administrative persons in private health institutions

Source:
Federal Law #323
(http://www.aipm.org/)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

China

Description of governing regulation or code(s)
•**R&D Based Pharmaceutical Association Committee (RDPAC) Code of Conduct:** Represents the key to walking the tight rope that is pharmaceutical promotion in China and only binds those who voluntarily sign up for membership
•Voluntary industry code
Others:
•SFDA: Drug Administration Law of the People's Republic of China
•Advertisement Law Article 15

Transparency clause
RDPAC Code of conduct
•**Article 6.4 RDPAC —** Speaker's fees in a contract must be reported and fees must be reasonable
•**Article 6.5.1 RDPAC —** Meetings venues and expenses - ensure events organized are focused on education
•**Article 2.5 RDPAC —** Reimbursement of doctors - expenses limited to transport, accommodation, meals and internet access
•**Article 6.5.2, 3 RDPAC —** Hospitality and entertainment - prohibition of entertainment, sports and leisure activities, e.g. golf, tennis, spa services theatre/opera, sightseeing, visits to museums, etc.
•**Article 6.5.3 RDPAC —** Meals - continue to be limited to 300 RMB per person
•**Article 6.5.3 RDPAC —** Gifts - inexpensive gifts. Gifts must relate to the festival and cannot be alcohol, tobacco or sporting/leisure tickets

Time frame
RDPAC
Effective since January 2011

Covered activities

•Speaker Fees

•Meetings venues and expenses

•Reimbursement of doctors

•Hospitality and entertainment

•Gifts

Source:
State Food and Drug Administration, P.R. China (http://eng.sfda.gov.cn/WS03/CL0766/61638.html)

Covered entities

•**Healthcare professionals —** Medical, dental, pharmacy or nursing professionals

•**Drug Purchasers**

•**Physicians**

•**Drug manufacturers, drug distributors or their agents**

•**Medical Institutions**

Proposed penalties
Violation of RDPAC

•Fines can range from 30,000 RMB — 100,000 RMB

•Also include up to 12 months suspension from RDPAC

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

India

Description of governing regulation or code(s)
•**Organization of Pharmaceutical Producers of India (OPPI):** A premier association of research and innovation driven pharmaceutical companies in India and also a scientific and professional body
•Voluntary industry code
Others:
•The Prevention of Corruption Act, 1988, Amendment 2008
•Central Drugs Standard Control Organization (CDSCO)
•Medical Council of India (MCI): Code of Ethics

Transparency clause
OPPI Code of Pharmaceutical Practices
•**Sec 7.5.2 —** Gifts — amendment institutes complete ban on gifts
•**Sec 7.1.2 —** Travel — no travel support except for speakers, consultants, advisors and investigators
•**Sec 7.1.6** Hospitality — no individual hospitality permissible for self/family members
•**Sec 7.5.1 —** Cash & monetary grants — no individual cash/monetary grants allowed except through approved institutions in a transparent manner with appropriate disclosure
•**Sec 9.1 —** Medical research — research can be conducted only after applicable regulatory, legal and other approvals
•**Sec 2.3 —** Endorsements — no public endorsements of drug permitted

Time frame
OPPI
Effective since 31 December 2012

Covered activities
•Events and Meetings
•Travel Facilities
•Entertainment
•Sponsorships
•Guests
•Hospitality
•Gifts
•Samples

Source:
Organization of Pharmaceutical Producers of India (http://www.indiaoppi.com/)

Covered entities

•**Healthcare professional -** Member of medical, dental, or nursing professions or any other person of his/her professional activities may prescribe, recommend or administer pharmaceutical products

•**Medical Institutions**

•**Pharmaceutical companies**

Proposed penalties
Violation of OPPI
•N/A
•Reputational Harm

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Australia

Description of governing regulation or code(s)

•**The Medicines Australia Code of Conduct (MACC) 17th Edition:** relates to the promotion of prescription-only medicines

•Voluntary industry code

Others:

•The Complementary Healthcare Council of Australia (CHC)

•The Australian Self-Medication Industry (ASMI) Code of Practice

Public disclosure

•**Sec-9.7.4 MACC** — Sponsoring company must request to disclose the sponsorship of sponsored healthcare professional presenting an oral presentation or poster at an educational or scientific meeting of colleagues

•**Sec-9.1.0 MACC** — The public disclosure of aggregate fees paid to consultants includes all payments in respect of hospitality, travel or accommodation. Name of consultants need to be disclosed

•**Sec 12.6 MACC** — Total fees, expenses and the like paid to healthcare professional consultants in relation to market research must be reported

The initial report covering from 1 Jan 2013 to 31 Mar 2013 must be submitted by 30 Apr 2013 and updated 6 monthly

Time frame

MACC

New code of conduct, effective on 11 January 2013

Covered activities

•Patient Support Programs

•Relationship with Health Consumer Organizations (HCOs)

•Educational events

- Description of Event
- Duration
- Venue
- Types of Professionals
- Type of Hospitality Provided
- Total Cost of Hospitality
- Final Number of Attendees

•Total Cost of Function

•Market Research

•Product specific media statements

Source:
The Medicines Australia Code of Conduct 17th edition (http://medicinesaustralia.com.au/)

Covered entities

•**Healthcare professionals**

•**Pharmaceutical industry**

•**Hospitals**

•**Health related organizations -** Education, training or academic purposes, medical research, activities that improve the quality use of medicines or improve patient outcomes

•**Healthcare organizations -** Relationship with patients

Proposed penalties

Violation of MACC

•Fine up to of a maximum of AUD 200,000

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Japan

Description of governing regulation or code(s)

•**Japan Pharmaceutical Manufacturers Association(JPMA):** Transparency guidelines for the relation between corporate activities and medical institutions

•Voluntary industry code

Others:

•JFMDA (Medical Device) and JGA (Generics)

Public disclosure

JPMA

•**Sec 2.4a —** R&D expenses — Joint studies, clinical trials and post-market clinical studies — total amount per year for the institution

•**Sec 2.4b —** Grants for scientific research — Scholarships, donations — institution name, # of instances per year, total amount per year

•**Sec 2.4c —** Manuscripts, lectures, speaking, consulting (honoraria) for individuals — HCP name, institution name, # of instances per year, total amount per year

•**Sec 2.4d —** Expenses for conferences, seminars, presentation meetings — # of instances per year, total amount per year

•**Sec 2.4e —** Hospitality expenses including social expenses, food, transportation, condolences — Total amount per year

Financial Year 2012 payments will be disclosed during FY 2013

Time frame

JPMA

Effective since 2012

Covered activities

•Research & Development (R&D) studies

•Post-marketing studies

•Speaker programs

•Meetings and events

•Dining

•Entertainment

•Gifts

•Donations

•Honoraria (speaker/advisor)

Source:

JPMA Promotion Code for Prescription Drugs (http://www.jpma.or.jp/english/)

Covered entities

•**Healthcare professionals** — Physicians, dentists, pharmacists, other healthcare professionals belonging to a medical institution, board members, employees who participate in choice or purchase of ethical pharmaceutical drugs in said institution

•**Healthcare organizations** — Hospitals, patient groups, medical association, medical institute, professional societies

•**Pharmaceutical companies**

Proposed Penalties

•**N/A**

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

South Africa

Description of governing regulation or code(s)

•**Pharmaceutical Industry Association of South Africa (PIASA) - Code of Practice -** The Pharmaceutical Industry Association of South Africa is a trade association of companies involved in the manufacture and/or marketing of prescription medicines

•Voluntary industry code

Others:

•Marketing Code Authority (MCA)

•Section 18C of Act 101 of the Medicines and Related Substance

Transparency clause

•**Clause 17-PIASA: Patient Support and or Group —** Companies may work with Patient organization, must ensure that involvement of the company is made clear so that all arrangements comply with code

•**Clause 18 — PIASA: Donations and Charities —** Companies are encouraged to have an agreement with the charity whereby disclosure is incumbent on both the parties. No donation may be made to hospitals or clinics as and incentive to prescribe any health product

•**Clause 20-PIASA: Medical Devices Samples —** Sponsor must disclose all costs for the duration of the equipment evaluation, including publications, lectures and other presentation

- The value of gifts should not exceed R 300 inclusive of VAT (general utility)
- For individual practicing HCP, should not exceed R 2,500 inclusive of VAT/year
- For training or academic institutions, it should not exceed R 10,000 inclusive of VAT/year

Time frame

PIASA

Effective since March 2011

Covered activities

•Gifts and Inducement
•Honoraria
•Travel(International, local)
•Events and Hospitality
•Meals and Accommodation
•Entertainment
•Grants and Donations
•Training and Education
•HCP paid service (Consulting, advisory board)
•Relationships between patient organizations

Covered entities

•Healthcare professionals
•Pharmaceutical companies
•Medical device manufactures

Proposed penalties

Violation of PIASA

•N/A

Source:

Pharmaceutical Industry Association of South Africa (http://www.piasa.co.za/)

**Please consult legal counsel for specific interpretation or assumptions regarding Country specific regulations or codes*

Questions?

Deloitte.


Official Professional Services Sponsor

Professional Services means audit, tax, consulting and financial advisory services.