INTERNATIONAL TRANSPARENCY DISCLOSURE

Quick Guide

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About this Compliance Quick Reference Guide

This Quick Reference Guide (the “Guide”) is intended to be just that—an easy-to-read-and-navigate guide of several international transparency disclosure/aggregate spend reporting requirements. The Guide reflects the global trend of increased transparency between the pharmaceutical and medical technology industries and healthcare professionals. It is important to note that transparency requirements are rapidly evolving. Therefore, the contents of the Guide may not be up-to-date.

Introduction

Since the passage of the U.S. physician payment sunshine act (now referred to as the “Open Payments” program), we have witnessed a proliferation of similar, “look-alike” laws, regulations and industry code requirements around the world. From Slovakia to Columbia, these developments are evolving at such an extraordinarily rapid pace that by the time you read this, something somewhere likely has changed! As these requirements are designed to promote transparency, mitigate conflicts of interest, and inform patients about their caregiver’s financial relationships with industry—i.e., all legitimate, non-partisan policy objectives—we should not expect these developments to slow down anytime soon.

To help keep track of these developments, we have created this compilation of pending and existing requirements relating to the reporting or public disclosure of certain transfers of value from manufacturers to so-called “covered recipients.” These requirements include national laws and regulations, country-specific industry codes, and the requirements of the new EFPIA pan-European pharmaceutical disclosure regime. The Guide is meant to provide an overview of the authoritative source of the disclosures, who must disclose, what must be disclosed, and when the disclosures must be made.

Important Notice

The information contained in this Compliance Quick Reference is provided to you “AS IS”, does not constitute legal advice, and should not be construed as legal advice or substitute therefor. We are not acting as your attorney. We make no claims, promises or guarantees about the accuracy, completeness, or adequacy of the information contained in this document or any website linked to document.

Transparency laws and codes are changing very rapidly and, accordingly, we do not guarantee that any information on this Quick Reference or our affiliated web sites is accurate and up to date. Nothing that you read or is provided in this Quick Reference should be used as a substitute for the advice of competent professional advice.
**Authority:**
Medicines Australia (Trade Association)

**Authoritative Source:**
Medicines Australia Code of Conduct (17th Edition)

**Effective Date:**
January 11, 2013

**Reporting Organizations/Individuals:**
IFPMA Member Companies (including Medicines Australia member companies).

**Reportable Parties/Covered Recipients:**
- Health care professionals and institutions
- Health care consumer organizations (HCOs)

**Reportable Information:**
- Consulting fees and advisory board fees paid to health care professionals or to their employers, or to third parties on their behalf; travel, hospitality and accommodation expenses paid or reimbursed
- Financial support and significant direct or indirect non-financial support for health consumer organizations
- Sponsorships to attend educational meetings and payments to speakers to give presentations and educational meetings

**Exclusions from Reporting:**
Fees for research and development work, including conduct of clinical trials

**Frequency of Reporting (and Reporting Date(s)):**
There are four (4) different types of reports that must be submitted each year to Medicines Australia. Consultancies report and HCO report are due annually by April 30. Advisory board and educational event reports are due every six months, by April 30 for the six-month period ended March 31 and by October 31 for the six-month period ended September 30.

**Penalties for non-compliance:**
The Code of Conduct contains procedures for non-compliance with the Code of Conduct. Sanctions include corrective action and penalties up to a maximum of $300,000.
Data Elements Required:

For advisory boards:
- the number of members
- honoraria/sitting fees
- costs of any hospitality
- accommodation (both within and outside Australia) and travel
- venue details and third party costs.

For consultancies:
- total number of consultancies per annum
- total cost of consultancy fees
- total number of consultants
- total costs of any hospitality
- total costs of accommodation and travel.

For educational events:
- information about each event sponsored including venue, type of health care professional attending;
- for sponsorships of individuals, type of costs supported; total number of individual recipients of support;
- total amount paid for each event;
- number of speakers receiving payment for presenting at an educational event, including any fees or honoraria, registration fees, costs of accommodation (both within and outside Australia) and travel related expenses in fees to speakers for each and the total number of speakers receiving payment.

For HCOs:
- the name of the health consumer organization;
- nature of the support;
- the monetary value of financial support and of invoiced costs.

For significant non-financial support that cannot be assigned a meaningful monetary value, the published information must describe clearly the non-monetary value that the organization receives.

Please refer to the Medicines Australia Code of Conduct (17th Edition):
Colombia

Authority:
Ministry of Health and Social Protection

Authoritative Source:
Draft Law

Effective Date:
Pending

Reporting Organizations/Individuals:
Manufacturers, distributors, importers, traders, or participants in the supply chain of drugs, supplies, devices, and medical equipment or any other health technology.
During Stage 1, registration of payments made to Health practitioners by reporting organizations is mandatory. Registration is required by all reporting organization during Stage 2.

Reportable Parties/Covered Recipients:
Health practitioners that prescribe health services, administrative staff that work in the health sector, health professional organizations, industry associations, clinics, hospitals or other entities providing health services that are related to the field of health services, students of professions in the health or related sector, universities, or other educational or research institutions in the health sector, student organizations of health sector professions, patients, patient organizations, non-government organizations, foundations, entities that evaluate technology assessment and clinical practice guidelines, health agencies, national and territorial entities, public officials, and any other entity or individual that participates in providing or receiving health services.

Reportable Information:
Direct payments and transfers of value of any type, including those made in cash and in kind. Indirect payments not made to the parties mentioned above but to a third party or intermediary, including natural or legal persons, also shall be registered.

Exclusions from Reporting:
- Payments by parties obligated to register made to someone with an employment or contractual relationship to develop the social objective of the activity of the payer shall not be registered.
- Medical samples or diagnostic tests shall not be registered “unless their individual market value exceeds four minimum wages (SMLMV).”
- Printed promotional information shall not be registered unless it is part of a continuing education or recreational activity.
- Transfers of value of less than half (1/2) a monthly legal minimum wage need not be registered, unless they exceed one monthly legal minimum wage in one year.
Frequency of Reporting (and Reporting Date(s)):
Stage 1: Payments made during 2015

- Registration 1: Will cover payments made during the first half of the year. Reports are due before October 31, 2015.
- Registration 2: Will cover payments made during the second half of the year. Reports are due before April 2016.

Stage 2: Payments beginning January 2016
- Reports will be made annually before April 30 of each year.

Penalties for non-compliance:
Failure to comply with the obligations established under this resolution will result in the application of penalties established in the law for the omission of the duty to register pursuant to the provisions of Articles 116 and 130 to 134 of Law 1438 of 2011.

Data Elements Required:
Stage 1: Voluntary disclosure of general information related to the payments to be disclosed.

- Mode of Payment:
  - Consulting fee
  - Compensation for services other than consulting
  - Fees
  - Gifts
  - Entertainment
  - Food and drink
  - Travel and accommodation
  - Education
  - Research
  - Charitable contributions
  - Royalties or licenses
  - Current or prospective ownership or investment interest
  - Direct compensation for serving on a faculty or as a speaker for a medical education program or academic event
  - Donation
  - Other

- Method of Payment:
  - Cash or cash equivalents
  - Services or items in kind
  - Shares, stock options, or any other interest in property, dividends, earnings, or other return on investment
  - Other

Stage 2: Required Disclosure of the Stage one field above in addition to:

- Identification of Healthcare Professional
  - Identifying data
  - Specialty
  - Identification number

- Product information associated with the payment
Denmark

Authorities:
Danish Health and Medicines Authority
Ethical Committee for the Pharmaceutical Industry (ENLI)

Authoritative Sources:
Executive Order dated July 15, 2008 under the Danish Medicines Act
Act No. 518 of May 26, 2014 (Act to amend the Medicines Act, the Act on medical equipment, pharmacies Act, Health Act and the Act on the marketing of health services)
Danish Ethical Rules for Promotion of Medicinal Products towards Health Care Professionals (ENLI Rules) (For Calendar Year 2014 reports)
“Danish Health Care Professionals (HCP) Sunshine Act” enhances the prescribed rules of Act. No 518.

Effective Date:
Executive Order: August 1, 2008
Act No. 518: November 1, 2014
Danish Sunshine Act: November 1, 2014
ENLI Rules: April 1, 2011

Reporting Organizations/Individuals:
Executive Order: Any holder of a marketing or manufacturing license under the Danish Medicines Act
Act No. 518: Extends the Executive Order obligations to manufacturers who market medical devices in risk class IIa, IIb or III medical devices for in vitro diagnostic or active implantable medical devices, representatives of manufacturers of such products, importers and distributors of such products established in Denmark.
ENLI Rules: Members of the Danish Association of the Pharmaceutical Industry (Lif), the Danish Generic Medicines Industry Association (IGL) and the Danish Association of Parallel Distributors of Pharmaceuticals (PFL) and their affiliates, and non-member companies agreeing to comply with the Rules.

Reportable Information:
Executive Order: Company must to the Danish Medicines Authority information regarding physicians, dentists or pharmacists that prescribe/dispense medicines to patients in Denmark and are associated with (i.e., provide services to) the company.
Act No. 518: Medical device companies must also report nurses that are associated with the company.
ENLI Rules: The following activities must be reported to the ENLI:
- Training or education organized or co-organized by the company, or
- Sponsorship of third party conferences sponsored by the Company
- Sponsorship of Danish HCPs to participate in third-party conferences
- Purchasing an exhibition stand at a conference in Denmark
- Provision of printed promotional material to HCPs (including website content in Danish)
Exclusions from Reporting:
Executive Order: Provision of a single, insignificant service (e.g. a one-time speaking engagement) in the calendar year, where the fee is proportionate to service provided. Services provided free of charge are also excluded unless there is a longstanding close relationship between the company and the service provider (e.g., director of the Company).

ENLI Rules: Pharmaceutical representative calls on HCPs; events where the HCP provides a service in return; website content available to the general public

Frequency of Reporting (and Reporting Date(s)):
Executive Order: Annually to the Medicines Authority by January 31

ENLI Rules: Reports for the following activities must be submitted at www.ENLI.dk using the standard report form within the following deadlines:
Company organized events: 10 working days after the event
Sponsorship of third-party conference or HCP: 10 working days after promise to provide financial support
Exhibit fee at conference: 10 working days prior to opening day of the conference
Promotional Material: The same day as the material is distributed or published

Penalties for non-compliance:
Violation of the Executive Order is punishable by a fine.

The ENLI Rules provide generally for sanctions in case of violations of the Rules by companies. In serious cases, fines or public reprimand may be imposed.

Data Elements Required:
Executive Order:
Name of covered recipient, professional or personal address, place of employment, CPR (Civil Registration) number, start and end dates of association with company.

The Medicines Authority may also require reporting companies to provide information about the nature and extent of the association as well as fees paid.

ENLI Rules:
Title of event, venue, city, country, opening and closing times,
Total cost per person of any meals provided in € incl. VAT.
Total cost of transport provided per person in € incl. VAT, plus arrival and departure dates.
Total cost of accommodation provided per person in € incl. VAT, plus hotel name and location.
Companies should attach program of event and company invitation to participants.
EFPIA (Europe)

Authority:
European Federal of Pharmaceutical Industries and Associations ("EFPIA")

Authoritative Source:
1. EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations ("HCP/HCO Disclosure Code")1
2. EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations ("PO Code")

Effective Date:
1. HCP/HCO Disclosure Code: January 1, 2015
2. PO Code: January 1, 2012

Reporting Organizations/Individuals:
EFPIA members, members of EFPIA subgroups and members of EFPIA member associations.

Reportable Parties/Covered Recipients:
1. HCP/HCO Disclosure Code: Any HCP or HCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.
   a. HCP: Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organization (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practicing HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.
   b. HCO: Any legal person (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organizations within the scope of the EFPIA PO Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.

2. PO Code: Patient organizations that operate in Europe. These are defined as not-for-profit organizations (including the umbrella organizations to which they belong), mainly composed of patients and/or caregivers that represent and/or support the needs of patients and/or caregivers.

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1 This "Disclosure Code" supplements the EFPIA’s “Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals” (the “HCP Code”) and “Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations” (the “PO Code”).
Reportable Information:
1. **HCP/HCO Disclosure Code:** Direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only Medicinal Products exclusively for human use.

2. **PO Code:**
   a. Financial support and/or significant indirect/non-financial support provided to patient organizations.
   b. Transfers of value provided to patient organizations that are engaged to provide significant contracted services.

Exclusions from Reporting:
1. **HCP/HCO Disclosure Code:** Transfers of Value that:
   a. are solely related to over-the-counter medicines;
   b. are not listed in Article 3 of the Disclosure Code, such as items of medical utility (i.e., educational materials) (governed by Article 9 of the EFPIA HCP Code), meals and drinks (governed by Article 10, especially Section 10.05 of the EFPIA HCP Code), medical samples (governed by Article 16 of the HCP Code); or
   c. are part of ordinary course purchases and sales of Medicinal Products by and between a Member Company and an HCP (such as a pharmacist) or an HCO do not fall within the scope of the disclosure obligation described in the Disclosure Code.

2. **PO Code:** None.

Frequency of Reporting (and Reporting Date(s)):
1. **HCP/HCO Disclosure Code:** Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year (the “Reporting Period”). Disclosures shall be made by each Member Company on the company website or a central platform within 6 months after the end of the relevant Reporting Period. First report will be due in 2016 (and the first reporting period shall be calendar year 2015).

2. **PO Code:** Disclosures shall be made publicly available on the company website and updated at least once a year.

Penalties for non-compliance:
1. Each Member Association will determine a system of sanctions in its national code, and enforce those sanctions on its members.

2. Sanctions to be proportionate to the nature of infringement, have a deterrent effect, and take into account repeated offenses.
Data Elements Reported:

1. HCP/HCO Disclosure Code: (see “Schedule 2 – Template” below)
   a. Identification of the Receiving Entity
      i. Name
      ii. Address (Street, City, Country)
      iii. Unique Country Local Identifier
   b. Donations and Grants to HCOs
   c. Contribution to costs of Events
      i. Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an event
      ii. Registration Fees
      iii. Travel & Accommodation
   d. Fee for service and consultancy
      i. Fees
      ii. Related expenses agreed in the fee for service or consultancy contract
   e. Research and Development Transfers of Value
   f. Total amount spent to each recipient
   g. Aggregate amount attributable to transfers of value to such Recipients (HCP and HCO)
   h. Number of Recipients (receiving certain transfers of value) (HCP and HCO)
      i. % of total transfers of value to individual HCPs & HCOs

2. PO Code:
   a. For Support
      i. Name of patient organization
      ii. Description of the nature of the support
      1. For significant non-financial support that cannot be assigned a meaningful monetary value the description must describe clearly the non-monetary benefit that the patient organization receives
      iii. Monetary value of financial support and of invoiced costs
   b. For Contracted Services
      i. Name of patient organization
      ii. Description of the nature of the services provided
      iii. Total amount paid per patient organization over the reporting period

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2 Actual data elements reported and format are based on the rules of the national association of the country where the HCPs place of business is located. These rules are based on the EFPIA requirements and template but the national associations can deviate to the extent required to comply with applicable national law (i.e., data protection rules). Therefore, you should consult the specific rules of the applicable member association. For a list of EFPIA member associations please visit [http://www.efpia.eu/about-us/membership](http://www.efpia.eu/about-us/membership)

3 This section identifies the standard template required by EFPIA. Each EFPIA Member Association, however, can modify the template, if necessary, to the extent that the standard template conflicts with applicable national laws or regulations.
According to EFPIA, as of December 9, 2014, the countries identified above have completed transposition of the HCO/HCO Disclosure Code.
France

**Authority:**
French Ministry of Social Affairs and Health
French Pharmaceutical Companies Association (LEEM)

**Authoritative Source:**
Law No. 2011-2012 of 29 December 2011 (“Loi Bertrand”)
Decree No. 2013-414 of 21 May 2013

**Effective Date:**
May 22, 2013

**Reporting Organizations/Individuals:**
Companies producing or marketing regulated medical and cosmetic products in France (includes both pharmaceutical and medical device manufacturers).

**Reportable Parties/Covered Recipients:**
Licensed Health Care Professionals and their associations, students for health care professions and their associations; patient associations; training institutions; health care institutions; foundations, learned societies, companies providing services related to health care products; publishers, broadcasters, and publishers of software for prescriptions.

**Reportable Information:**
Any advantages (benefits) equal to or in excess of 10 Euros provided to a covered recipient, and any contract (convention) entered with a covered recipient.

**Exclusions from Reporting:**
Contracts for the sale of goods and services from companies subject to the reporting obligation.

**Payments for services rendered.**

**Frequency of Reporting (and Reporting Date(s)):**
Advantages must be reported twice annually (by August 1 for advantages provided January 1 – June 30 and by February 1 of the following year for advantages provided July 1 – December 30) to a website maintained by the Ministry of Health (https://www.entreprises-transparence.sante.gouv.fr).

Contracts are reported within 15 days of execution.

Information is published twice annually, by April 1 and October 1 of each year.
Penalties for non-compliance:
Fines of up to 45,000 Euros

Data Elements Required:
Advantages: Type of advantage, value, date of transfer, nature
Contracts: Date and purpose of contract
Covered recipient information:
  - Type of covered recipient
    - For individual HCPs: name, title or profession, professional address, specialty, RPPS number
    - For students: Name, training institution, RPPS number
    - For entities: name of entity, type of entity, address, ID number (e.g., SIREN or FINESS)
Hungary

Authority:
Law: Hungarian National Law
Code(s): Association of Innovative Pharmaceutical Manufacturers

Authoritative Source:
Act XCVIII of 2006 on the Safe and Economic Supply and Distribution of Medicines and Medical Aids and the Distribution of Medicinal Products
Code of Ethics for Pharmaceutical Marketing Communications (Transposed EFPIA PO Code)
AIPM Transparency Code on the Disclosure of Transfers of Value from AIPM Companies to Healthcare Professionals and Healthcare Organizations (Transposed EFPIA Disclosure Code on Transfers of Value)

Effective Date:
Law: December 29, 2006
Code of Ethics: July 1, 2014

Reporting Organizations/Individuals:
Law:
- Holders of the marketing authorization of a medicinal product or therapeutic medical device, authorized distributors of a medicinal product or therapeutic medical device, manufacturers or distributors of medical aid or another economic operator on behalf of the aforementioned

Reportable Parties/Covered Recipients:
Law:
- Healthcare professionals and persons engaged in the supply and distribution of medicinal products and/or medical aids

Reportable Information:
Law:
- Sponsorship of HCPs to attend professional conferences or courses

Frequency of Reporting (and Reporting Date(s)):
Law: At the latest, ten days before the event.

Exclusions from Reporting:
N/A
Penalties for non-compliance:
Law: Subject to investigation by the government body for pharmaceuticals and further discipline

Data Elements Reported:
Law: The following must be submitted to the National Institute for Quality and Organizational Development in Healthcare and Medicines ("GYEMSZIOGYI")

- The name, location, date and program of the proposed event
- The beneficiary's name
- The amount of the subsidy, the cost of organization
- The reason for using that particular location
- Related supplementary program including the name, date, location and brief description

Additionally, the following documents must be included:

- A copy of the document in proof of payment of the entry fee, or a copy of the document evidencing prior registration;
- Copies of contracts concluded in connection with staging the event;
- Copies of documents in proof of the amount of support provided for or the costs of organization of the event;
Japan

Authorities:
Japan Pharmaceutical Manufacturers’ Association (JPMA)
Japan Federation of Medical Device Associations (JFMDA)

Authoritative Sources:
JPMA Promotion Code (Industry Code)
- Transparency Guideline for the Relation between Corporate Activities and Medical Institutions ("Transparency Guideline")
- Guideline for Transparency of Relationships between Corporate Activities and Patient Groups ("Patient Group Transparency Guideline")

JFMDA Promotion Code (Industry Code)
- Transparency Guideline for the Medical Device Industry in its Relationships with Medical Institutions and Other Organizations ("Medical Device Transparency Guideline")

Effective Date:
- Transparency Guideline: January 2011 (first disclosures in 2013)
- Medical Device Guidelines – First disclosures in 2014

Reporting Organizations/Individuals:
Members of JPMA (Japan Pharmaceutical Manufacturers’ Association) and JFMDA (Japan Federation of Medical Devices Associations)

Reportable Parties/Covered Recipients
Healthcare professionals and medical institutions

Reportable Information:
- Research and Development Expenses
  - Joint research expenses: Total annual amount
  - Commissioned research expenses: Total annual amount
  - Clinical trial expenses: Total annual amount
  - Post-marketing clinical trial expenses: Total annual amount
  - Adverse events, infection case reporting expenses: Total annual amount
  - Post marketing surveillance expenses: Total annual amount
- Academic Research Support Expenses
  - Scholarship donations: Total annual number and the total amount of donations per research institution (department)
  - General donations: Total annual number and the total amount of donations per research institution
  - Academic conference donations: Total amount of donations per academic conference
  - Cosponsored academic conference hosting expenses: Total amount of expenses per academic conference

- Manuscript writing, etc.
  - Lecture fees: Total annual amount, and total annual number and the total annual amount of fees paid per healthcare professional
  - Manuscript, writing fees: Total annual amount, and total annual number and the total annual amount of fees paid per healthcare professional
  - Consulting fees: Total annual amount, and total annual number and the total annual amount of fees per healthcare professional

- Expenses for Information Provision
  - Lecture expenses: Total annual number and the total annual amount of expenses
  - Seminar expenses: Total annual number and the total annual amount of expenses
  - Medical literature provision expenses: Total annual number and the total annual amount of expenses

- Other Expenses
  - Receptions and other social courtesies: Total annual amount

Patient Organization Transparency Guideline (pharma only):
- Direct support: monetary donations and contributions, dues from members and supporting members, advertising expenses, etc. Name(s) of patients association(s) and total annual amount(s) by expense item
- Indirect support: Expenses related to lectures, informational meetings, training sessions, and other gatherings. Name(s) of patients association(s) and total annual amount(s)
- Payments to third parties in support of patients associations: Name(s) of patients association(s) and total annual amount(s)
- Lecturer honoraria and fees related to manuscript writing/supervising, surveys, consulting

Frequency of Reporting (and Reporting Date(s)):
Annually per company guideline

Penalties for non-compliance:
No penalties

Additional Information:
Each company is to develop its own internal guideline based on the foregoing framework, and secure consents to disclosure from covered recipients (e.g., in contracts).

Disclosures are to be made on company websites
Netherlands

Authority:
Foundation for the Code of Pharmaceutical Advertising (CGR)
Dutch Foundation for Medical Technology Companies

Authoritative Source:
Code of Conduct for Pharmaceutical Advertising
Dutch self-regulatory Code of Conduct for Medical Devices (GMH)

Effective Date:
Pharmaceutical Code: May 16, 2014; January 1, 2015 (for transparency provisions regarding Patient Organizations)
Medical Device Code: January 1, 2015

Reporting Organizations/Individuals:
A transparency register was set up by the Foundation for the Code for Pharmaceutical Advertising (CGR). All healthcare professionals, healthcare institutions and authorization holders that are affiliated with the following participating umbrella organizations take part in the register:

Nefarma (Association for Innovative Medicines in The Netherlands)
Bogin (Association of the Dutch Generic Medicines Industry)
Neprofarm (Association of the Pharmaceutical Industry for Self-Care Medicines and Healthcare Products)
KNMG (The Royal Dutch Medical Association)
KNMP (The Royal Dutch Pharmacists Association)
V & VN (The Dutch Nurses Association)
NAPA (The Netherlands Association of Physician Assistants)
NVZ (The Netherlands Association of Hospitals)
NFU (The Netherlands Federation of University Medical Centers)
OMS (The Netherlands Order of Medical Specialists)
LHV (The Netherlands National Association of General Practitioners)

A small number of healthcare providers and authorization holders are not affiliated with one of the above organizations. They have been, and are explicitly invited to voluntarily report any financial relationships.

Beginning January 1, 2015, suppliers of Implantable Cardioverter Defibrillators (ICDs), pacemakers, stents and/or hip and knee prostheses are also required to disclose financial relations with Physicians that are included in the Dutch public register of HCPs (BIG-register) with the title “cardiology” or “orthopedics
Reportable Parties/Covered Recipients:
The code of conduct requires that arrangements be made for the disclosure of service and sponsorship relationships agreed between authorization holders and healthcare professionals, groupings of healthcare professionals and entities by which healthcare professionals participate or by which they are employed.

Beginning January 1, 2015, support for patient organizations by an authorization holder must also be disclosed.

Reportable Information:
Financial relationships between healthcare professionals, healthcare institutions, patient organizations and authorization holders.

- Services - A physician or healthcare professional can for example give a lecture or presentation, or write a medical-scientific piece for which he or she receives remuneration from a pharmaceutical company.
- Sponsorship - A pharmaceutical company can for example provide financial support for a project or a particular piece of research in exchange for acknowledgment in the relevant publications.

Disclosure is compulsory if the healthcare professional, partnership or institution in question receives more than € 500 (in money or in kind) from a pharmaceutical company in any calendar year.

Frequency of Reporting (and Reporting Date(s)):
Disclosure must occur within the first three months of the end of the calendar year.

Exclusions from Reporting:
Reporting is voluntary for payments (in money or in kind) totaling less than € 500 from an authorization holder in any calendar year.

Penalties for non-compliance:
Self-regulation.

Data Elements Reported:
- The name of the healthcare professional, partnership or institution concerned (that performed the services);
  - For healthcare professionals: the name, specialization and work address
  - For groupings of healthcare professionals or entities: name, registered address and/or Chamber of Commerce number
- The name of the authorization holder concerned;
  - Name and business address and/or the Chamber of Commerce number
- The nature of the financial relationship;
  - Nature of the agreement (selected from one of categories below)
- The amount;
  - Total amount paid in the calendar year (in Euros)
- The year to which the relationship relates.
<table>
<thead>
<tr>
<th>Service Provision, Consultancy</th>
<th>General individual consultancy work, also including writing articles/ scientific lectures commissioned by a third party</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service Provision, Advisory</td>
<td>Participation in an advisory board, being a gathering of healthcare professionals at which they advise the company concerned</td>
</tr>
<tr>
<td>Service Provision, Speaker</td>
<td>Acting as a speaker/giving a presentation</td>
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<tr>
<td>Service Provision, Research not subject to the WMO</td>
<td>Carrying out research that is not subject to the WMO</td>
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<td>Service Provision, Other</td>
<td>Other forms of service not covered by one of the other categories</td>
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<td>Sponsoring an event</td>
<td>Sponsoring an event not organized by an authorization holder</td>
</tr>
<tr>
<td>Sponsoring other</td>
<td>Sponsoring innovative and/or quality-enhancing activities aimed at directly or indirectly improving patient care or advancing medical science and which are not funded (or not fully funded) in any other regular manner</td>
</tr>
</tbody>
</table>
Portugal

Authority:
National Authority of Medicines and Health Products, IP (“INFARMED”)

Authoritative Source:
O Decreto-Lei n.º 20/2013, de 14 de fevereiro, e o Decreto-Lei n.º 128/2013, de 5 de setembro (“The Decree-Law n.º 20/2013, of February 14, and Decree-Law n. 128/2013 of 5 September”)

Effective Date:
February 14, 2013

Reporting Organizations/Individuals:
Organizations covered by the Portuguese Medicinal Products Act. These organizations include:

1. Manufacturers.
2. Holders of marketing authorizations.
3. Distributors.
4. Parallel traders of medicinal products.
5. Pharmacies that proceed to payment of any value.
6. Medical associations or any other type of entity, representative of a particular group of patients, and
7. Scientific or clinical trials companies, associations or societies.
8. Any other entity, natural (healthcare professionals, such as physicians, dentists, pharmacy technicians, nurses) or legal person (private or public)

Reportable Parties/Covered Recipients:
1. Medical associations or any other type of entity, representative of a particular group of patients, and
2. Scientific or clinical trials companies, associations or societies.
3. Any other entity, natural (healthcare professionals, such as physicians, dentists, pharmacy technicians, nurses) or legal person (private or public)

Reportable Information:
Any subsidy, sponsorship, donation or any other value, asset or right assessable in money with a value of over €60 must be reported to INFARMED.

Exclusions from Reporting:
1. All payments that are made pursuant to service agreements and employment contracts.
2. Any regular and periodic payments in cash or in kind that are due as a remuneration when the provider of the service depends economically of the payer.

Frequency of Reporting (and Reporting Date(s)):
Within 30 working days counting from the day the subsidy, amount or similar is granted or received.
Penalties for non-compliance:
1. Failure to comply with the report obligations, retention of supporting documentation, including action programs or events, gives rise to the following fines:
   a. from € 2,000 up to € 180,000 to be determined by INFARMED

Data Elements Reported:
1. Identification of the Receiving Entity
   a. Name
   b. Address
   c. Postcode
   d. Country
   e. E-mail

2. Characterization of Acceptance
   a. Full name of Event / Property / Action
   b. Contribution Type
   c. Acquisition value (in €)
   d. Start Date
   e. End Date
   f. Remarks

3. Identification of the Contributor
   a. Type of Entity
   b. Name
   c. NIF
   d. Address
   e. Postcode
   f. Country
   g. E-mail
Romania

**Authority:**
Law: Romania Ministry of Health
Code(s): Associatia Romana A Producatorilor Internationionali de Medicamente (ARPIM)

**Authoritative Source:**
Emergency Ordinance no. 2 of 29 January 2014 on amendment of Law no. 95/2006 on healthcare reform and of certain regulatory acts
ARPIM HCP/HCO Disclosure Code (Implemented EFPIA Disclosure Code on Transfers of Value)
ARPIM Code of Ethics

**Effective Date:**
Law: February 11, 2014
Disclosure Code: January 1, 2015

**Reporting Organizations/Individuals:**
Law:
- Manufacturers, marketing authorization holders or their representatives to Romania and wholesale and retail distributors of medicinal products, medical devices and healthcare material.

Code of Ethics:
- Member Pharmaceutical companies

**Reportable Parties/Covered Recipients:**
Law:
- Physicians, medical assistants, professional organizations, patient organizations and any other types of organizations in the healthcare system

Code of Ethics:
- Healthcare Professionals and Healthcare Organizations
Reportable Information:
Law:
Requires reporting parties to notify the Ministry of Health and the National Agency for Medicines and Medical Devices on all sponsoring activities as well as on any other expenses paid for physicians, medical assistants, professional organizations, patient organizations and any other types of organizations in the healthcare system.

Code of Ethics:
Requires Member Companies to report medicine donations to medical institutions to the ARPIM Ethics Group
Suggests Member Companies report donations, sponsorships, and/or loans (commodatus) to the ARPIM Ethics Group and to publically disclosure the support.

Exclusions from Reporting:
N/A

Frequency of Reporting (and Reporting Date(s)):
Code of Ethics:
Disclosures of medicine donations shall be made twice a year in January and July.

Disclosures of donations, sponsorships and/or loans (commodatus) shall be made once a year but should be reported to the ARPIM Ethics Group prior to giving the donation, sponsorship, and/or loan.

Penalties for non-compliance:
The Codes contains procedures for non-compliance with the Codes.

Data Elements Reported:
Law: Form for Declaration of Sponsorship must be submitted. Forms may be found on the National Agency for Medicine and Medical Devices (NAMMD) website (pending).

Disclosure Code: Disclosures are made pursuant to the EFPIA HCP/HCO Disclosure Code

Code of Ethics:
1. Medicine Donations:
   a. Company Name
   b. Product Name
   c. INN (Nonproprietary International Name)
   d. Concentration
   e. Pharmaceutical Form
   f. Unit/package
   g. Date of donation
   h. Beneficiary
   i. Quantity
   j. Value (RON with VAT included)

2. Sponsorship, Donations, or Loans
   a. Company
   b. Date of Sending to Ethical Environment Work Group
   c. City/District
   d. Sponsorship beneficiary
   e. Name of Contact Person
   f. Object to be sponsored
g. Value (RON with VAT included)
h. Details/Purpose
Slovakia

**Authority:**
Law: Slovak Ministry of Health
Code: Slovak Association of Innovative Pharmaceutical Research (AIFP)

**Authoritative Source:**
Law No. 362/2011 Coll. on medicinal products and medical devices
Code of Ethics of the Pharmaceutical Industry in Slovakia (Implements EFPIA HCP/HCO Disclosure Code)

**Effective Date:**
Law: December 1, 2011
Code: January 23, 2015

**Reporting Organizations/Individuals:**
Manufacturers and distributors of medicinal products and medical devices

**Reportable Parties/Covered Recipients:**
Healthcare providers

**Reportable Information:**
Requires manufacturers to submit a report to the Ministry of Health "on the level of expenditure on promotion, marketing and non-monetary benefit-provided, directly or indirectly, to the health care provider during the previous year."

Requires notification to the National Health Information Centre a list of HCP participation/attendance at professional/scientific or educational events.

**Exclusions from Reporting:**
None

**Frequency of Reporting (and Reporting Date(s)):**
Annually, by January 31

**Penalties for non-compliance:**
Administrative offense for failure to submit

**Data Elements Reported:**
Reports to the Ministry of health shall include the name and address of the recipient and the value of the benefits.

Notifications to the National Health Information Center shall include a list of the first name, last name and address of HCPs who have participated in professional/scientific or educational events that were financed by a manufacturer or third party.
United States of America (USA)

**Authority:**
Center for Medicare & Medicaid Services (CMS)

**Authoritative Source:**
Public Law 111-148 Sec. 1128G.\(^5\)

**Effective Date:**
May 23, 2010

**Reporting Organizations/Individuals:**
Manufacturers, marketing authorization holders or their representatives to the U.S and wholesale and retail distributors of medicinal products, medical devices and healthcare material, who sell, produce or advertise their products in the U.S.\(^7\)

**Reportable Parties/Covered Recipients:**
As mentioned in Subsection (e) (6)(A) covered recipients are all physicians and teaching hospitals, or to an entity or individual at the request of or designated on behalf of a covered recipient, in the health care system.

**Reportable Information:**
Requires manufacturers to submit a report to the CMS on a aggraded level including a description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (b), during the preceding year.

**Exclusions from Reporting**
None

**Frequency of Reporting (and Reporting Date(s)):**
- Annual Reporting not later than the 90\(^{th}\) day of each year

**Penalties for non-compliance:**
- Reporting not on time:
  - Up to 10’000 USD (max. per year 150’000 USD)
- Non-compliance on purpose:
  - 10’000 USD to 100’000 (max. per year 1’000’000 USD)

**Data Elements Reported:**
- Name
- Business Address
- Value of transfer/ payment
- type of payment
- Date of the payment
- Description of the nature of the payment

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\(^7\) Sec 1128G (e)(1)
About ARCONDIS

ARCONDIS is the largest consulting company exclusively specialized in the life sciences industry in the DACH region (German speaking countries). We have been managing challenges and projects for our customers in the areas of compliance, information management and IT management since 2001. In so doing, we create added value through cross-functional, sophisticated concepts and intelligent implementation under consideration of regulatory aspects.

Our many years of experience in regional and international projects in the field of life sciences and our methodical-pragmatic approach build the foundation for our exceptionally multifaceted services. With interdisciplinary teams and project experience in 2,500 orders for over 135 corporations and small to medium businesses, we have a unique mix of competencies. We believe that people make the difference, and we give our employees a strong foundation upon which to jointly achieve success with our customers in a very challenging environment.


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