A Tour of Various National Reporting Mandates

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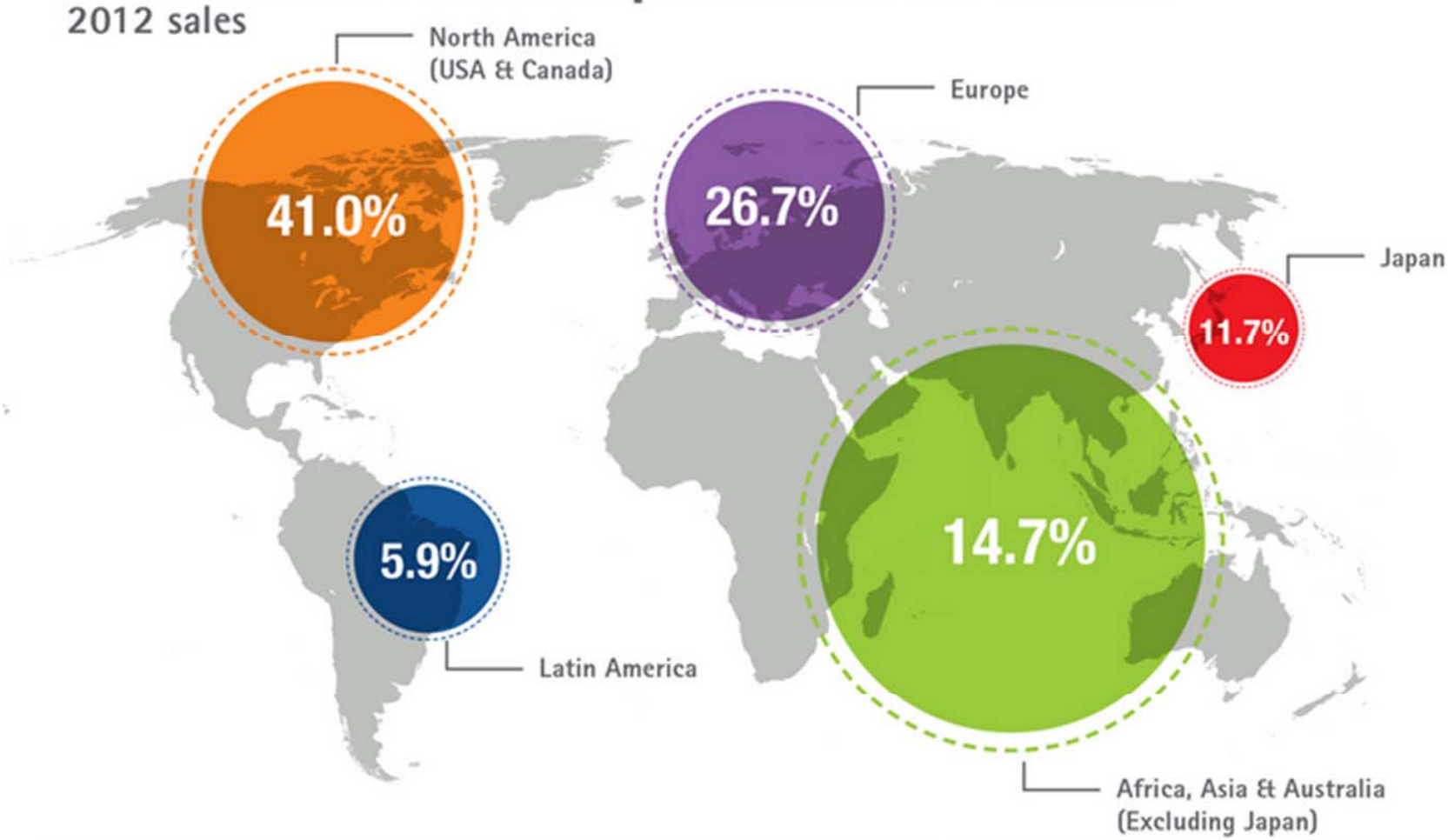
The 4th Annual Global Transparency Reporting Congress
April 8-9, 2014
London, UK

Breakdown of the World pharmaceutical market

2012 sales



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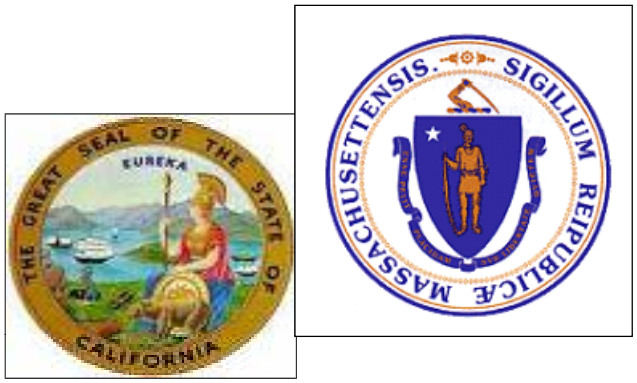
EFPIA, Review of 2012 and Outlook for 2013

Regulating Bodies



MEDICINES Australia

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Timing of Disclosure

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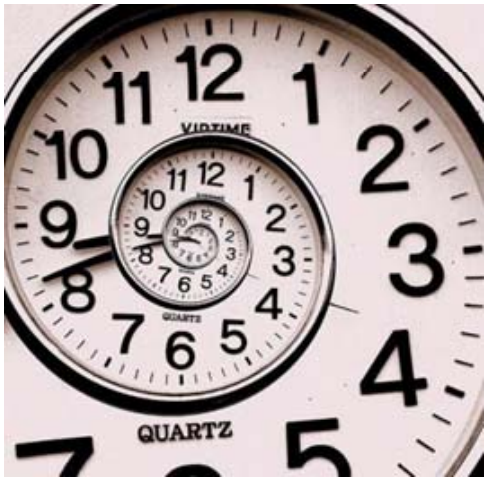
Timing of Disclosure

- United States – Annual
- EFPIA – Annual
- France – Biannual/15 days
- Portugal – 30 days
- Netherlands – Annual
- Japan – Annual



- Australia

Annual

Biannual

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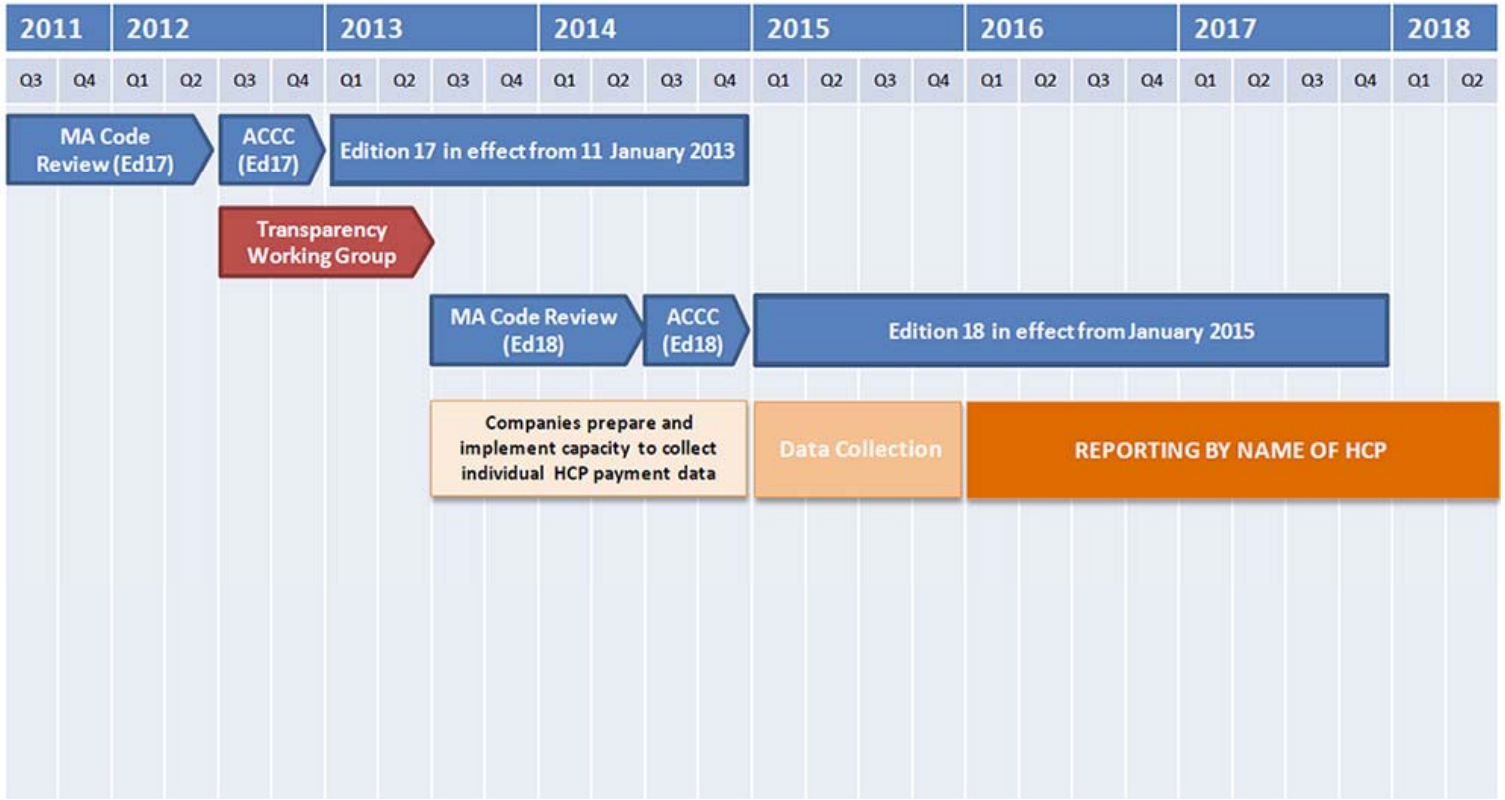
Australia

TIMELINE CODE OF CONDUCT
TRANSITION TO GREATER TRANSPARENCY



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Spend Detail

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Spend Detail

- United States – Individual
- EFPIA – Individual/Aggregate
- France – Individual
- Portugal – Individual
- Netherlands– Individual
- Japan – Individual/Aggregate

- **Australia** → Aggregate / Individual

?

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Who's Covered?

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United States

- Key Term: Covered Recipients
  - Physicians:
    - Any physician, except for a physician who is a *bona fide* employee of the applicable manufacturer that is reporting the payment.
    - Doctors of medicine and osteopathy, Dentists, Podiatrists, Optometrists, and Chiropractors.
  - Teaching Hospitals
    - Any institution that received a payment under 1886(d)(5)(b), 1886(h), or 1886(s) of the Act during the last calendar year for which such information is available.
    - List published annually by CMS.

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France

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

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EFPIA

- Healthcare Organisations:
  - Any legal person (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations 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.
- Healthcare Professionals:
  - 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 organisation (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 practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.
- Patient Organisations:
  - Not-for-profit organisations (including the umbrella organisations 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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Australia

- Healthcare professional consultant: "a healthcare professional engaged by a company to provide services or advice for a fee (not an employee of the company)."
- Healthcare professions and healthcare professionals: "includes members of the medical, dental, pharmacy or nursing professions and any other person who in the course of their professional activities may prescribe, dispense, recommend, supply or administer a Product."
- Health consumer organisations: "not-for-profit organisations that represent the interests and views of consumers of health care. They may range from small volunteer groups to large organisations, and generally promote views that are independent of government, the pharmaceutical industry and professional health service providers."

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Who Has To Report?

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United States

- Key Term: Applicable Manufacturers

  An entity that is operating in the United States that falls within one of the following categories:

  - An entity engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply…. This definition does not include distributors or wholesalers (including, but not limited, re-packagers, re-labelers, and kit assemblers) that do not hold title to any covered drug, device, biological or medical supply.
  - An entity under common ownership with an entity in paragraph (1), which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

- Key Term: Covered Drug

  Any drug, device, biological, or medical supply for which payment is available under Medicare, Medicaid, or CHIPs (or a waiver of such plan), either separately (such as through a fee schedule of formulary) or as part of a bundled payment (for example, under hospital inpatient prospective payment system or the hospital outpatient prospective payment system) and which is of the type that in the case of a:

  - Drug or biological, by law, requires a prescription to be dispensed; or
  - Device (including a medical supply that is a device), by law, requires premarket approval by or premarket notification to the FDA.

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United States

- Key Term: Group Purchasing Organizations ("GPOs")

  An entity that:
  - Operates in the United States; and
  - Purchases, arranges for purchase, or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the purchasing entity itself.

<u>Operating in the U.S.</u> means that the entity has a physical location within the U.S. or otherwise conducts activities in the U.S., either directly or through a legally authorized agent.

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France

- Companies marketing or producing one or more of the following products are affected:
  - Healthcare products intended for human use:
    - Medical products including insecticides, acaricides, and pesticides for human use, medicines prescribed by physicians or hospitals, and patient medicines, narcotic or psychotropic or other poisonous substances used in medicine, essential oils and medicinal herbs, raw materials for pharmaceutical use;
    - Biomaterials and medical devices; and
    - Various others.
  - Products for cosmetic uses
    - Non corrective contact lenses, cosmetic products, tattoo products.

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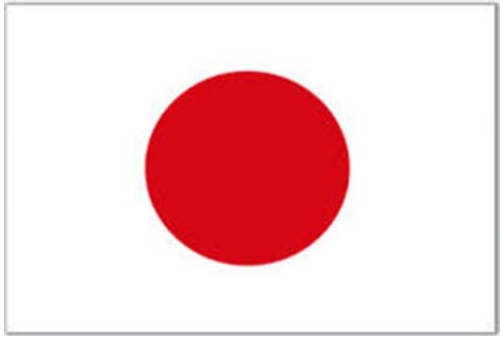
EFPIA, Australia & Japan

- Members of Industry Groups

- Non Members?



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What Has To Be Reported?

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Transfer of Value – United States

- The Sunshine Act Definition:
  - **Payment or Other Transfer of Value:**
    - **A transfer of <u>any thing</u> of value**
      - This includes any direct or indirect payment or other transfer of value provided to a covered recipient or any payment provided to a third party on behalf of a covered recipient (e.g. honorarium, food, travel cost, textbooks, scientific reprints, etc.)
      - Research payments included, reported separately
      - Ownership and investments interests included, reported separately
      - All TOVs are included, unless explicitly excluded from reporting requirements.

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Transfer of Value – EFPIA

- EFPIA Definition:
  - Transfers of Value: 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. Direct transfers of value are those made directly by a Member Company for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, or transfers of value made through an intermediate and where the Member Company knows or can identify the HCP/HCO that will benefit from the Transfer of Value.

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Meals

- Not Reported
- Monetary Threshold

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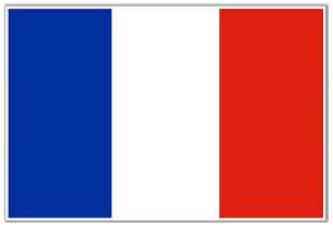
France
Agreements and Benefits



- Agreements: Companies must report to the public authority certain information on agreements within fifteen days of the signing of the agreement.
- Benefits: Relevant information for benefits must be reported biannually: by August 1 for benefits provided from January to June of a calendar year, and by February 1 for benefits provided from July through December of the preceding calendar year.
  - Direct or indirect, in kind or in cash, benefits that equal to or exceed ten Euros, inclusive of VAT, have to be reported. Benefits worth less than ten Euros do not have to be disclosed.

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Netherlands

- Types of financial relationships between companies and healthcare professionals that must be disclosed are:
  - Service agreements with professionals or partnerships/associations of professionals/institutions including:
    - Consulting
    - Advisory
    - Speaker
    - Non-WMO-speaker research
    - Other

Sponsorship agreements of meetings between a company and associations of professionals/institutions that directly or indirectly improve healthcare to patients or the promotion of medical science.

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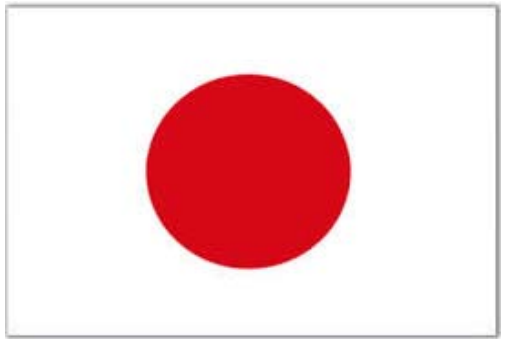
Japan



- Payments to be disclosed:
  - R&D – related costs – Annual Payment/Aggregate
  - Grants/Donations – Annual Payment for Grantee Group
  - Honoraria (Speaking, Writing & Consulting) – Annual Payment for Individual
  - Information Exchange Costs (i.e. speaker programs) – Annual Payment/Aggregate
  - Meals and Hospitalities Provided to HCPs – Annual Payment/Aggregate

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Australia

Australia: Code of Conduct (Edition 17)			
Advisory Board Reports	**Educational Event Reports**	**Health Professional Consultant Reports**	**Health Consumer Organisation Reports**

• Appendix 4
• Reports are submitted every 6 months
• Reporting Periods:
  • April – September
  • October – March
• Deadlines: Within 1 month of the reporting period ending
	• Appendix 3
	• Reports are submitted every 6 months
	• Reporting Periods:
	  • April – September
	  • October – March
	• Deadlines: Within 1 month of the reporting period ending
		• Appendix 5
		• First **annual** report due 30 April 2014
		• Reporting Period:
		  • Previous calendar year (2013)
		• Reporting Frequency: Annual – 30 April
			• Table 10
			• First **annual** report due 30 April 2014
			• Reporting Period:
			  • Previous calendar year (2013)
			• Reporting Frequency: Annual – 30 April

Updates:

- Edition 17: Effective 11 January 2013
- Code of Conduct Guidelines Version 4 (February 2014)
- Edition 18: Effective January 2015 (Anticipated)

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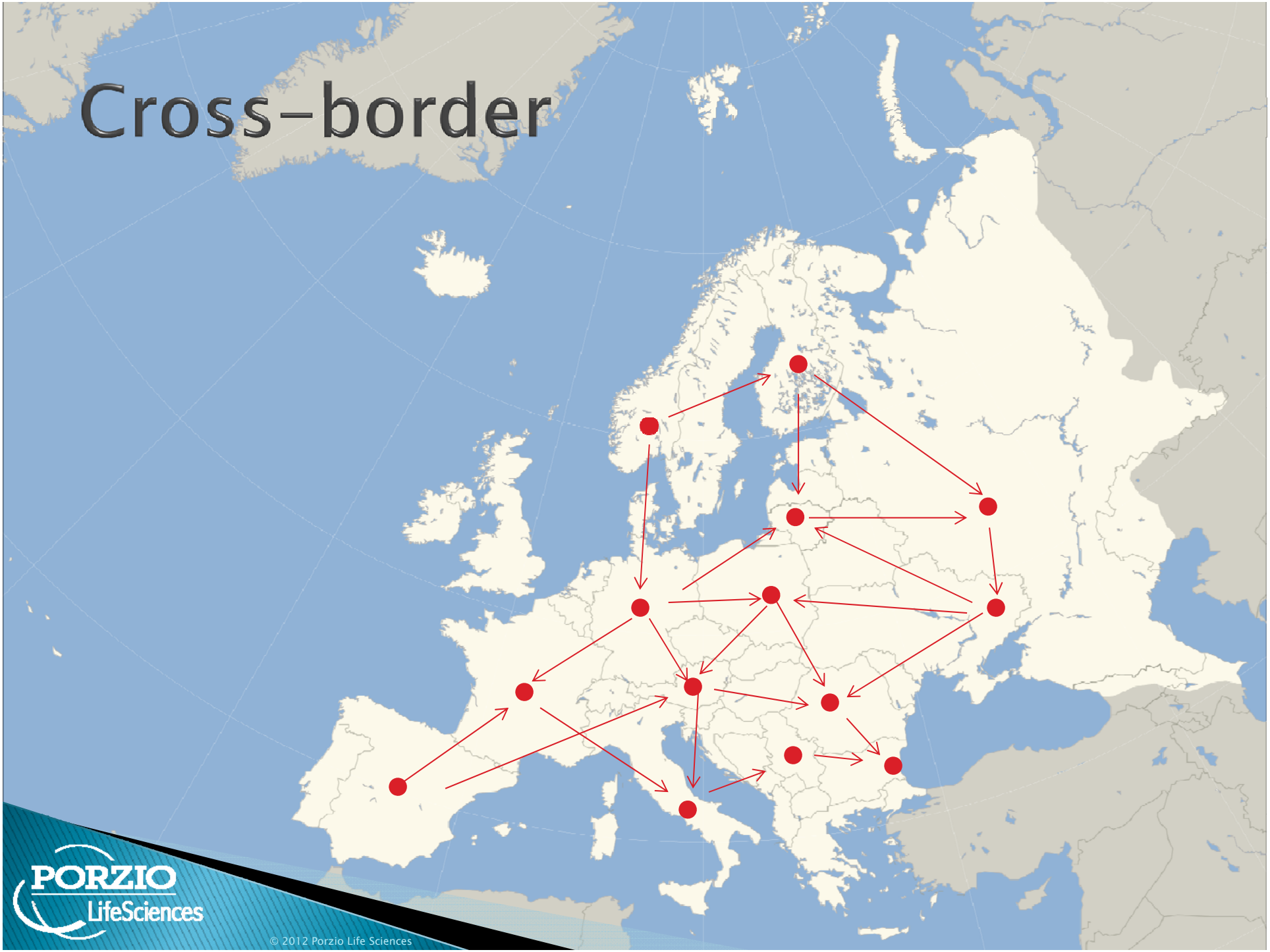
More Information available at:
http://medicinesaustralia.com.au/code-of-conduct/education-events-reports/

Cross-border



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Consent and Dispute

- Importance of consent
  - EFPIA: When making a Transfer of Value to a HCP/HCO, and in their written contracts with HCPs/HCOs, companies are encouraged to include provisions relating to the Recipient's content to disclose Transfers of Value in accordance with the provisions of the EFPIA HCP/HCO Disclosure Code.

- Dispute Process
  - United States: 45 day Review + 15 Day Correction Period
    - CMS will provide notification to manufacturers, GPOs and covered recipients when the data is ready to review.
    - Covered Recipients and Physician Owners may review data and initiate a dispute during the 45-day period.
    - If a dispute is resolved within the 45 days or the extra 15 days following the 45 day review period, CMS will publish the corrected data.
    - If a dispute in the data cannot be resolved within 15 days following the 45 day review period, CMS will post the manufacturer's data as submitted and mark it as disputed.

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Concluding Thoughts

- There will be more, not less, transparency around the world
- Self-regulatory codes v. legislation
- Anticipated use of data
- Impact of the US experience
- Will the medical device industry follow the lead of the pharmaceutical industry
- Data Privacy

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