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ARNOLD & PORTER LLP

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## Developing International Transparency Regulations

Dan Kracov

Jeff Handwerker

Jack Tanselle

National Disclosure Summit

March 26, 2012

NAVIGANT



# Australia

## (MA) Medicines Australia Association Code of Conduct – Disclosure Requirements


- **Pharmaceutical Companies** agree to report details of **Educational Events** including a description of the event, duration of educational content, venue, professional status of attendees, cost and type of hospitality provided, number of attendees and total cost of the function
- Gifts, entertainment and lavish hospitality to doctors are prohibited
- Required by Australian Competition & Consumer Commission (ACCC)
- **Public Disclosure** made every **6 months** starting with the period from July 1, 2007 through December 31, 2007

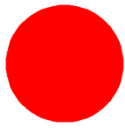


# France



## Law No. 2011-2012 on Strengthening the Safety of Drug and Health Products

- Applies to **Pharmaceutical, Medical Device, Cosmetic Companies and Distributors**
  - Contractual arrangements, written and spoken publications, and any other benefits granted to the following must be **publically disclosed**:
    - Healthcare Professionals, Hospitals, Patient Associations, or Providers of Medical Software
  - Adopted on December 29, 2011
    - Not enforceable until after additional details expected late 2012
    - However may be **retroactively applied back to January 1, 2012**
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# Japan

## (JPMA) Japan Pharmaceutical Manufacturers Association - Transparency Guidelines

- **Pharmaceutical Companies** agree to report:
  - Aggregated payments for R&D, Speaker Programs, Dining, Entertainment, Gifts, Meetings
  - Annual amount per recipient/organization for grants, donations, research funding and honoraria (e.g. consulting fees)
- Voluntary Guidelines, all members of JPMA agreed to comply
- First declaration to be made in 2013 for **payments in 2012** on **company's own website**






# Netherlands

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## CGR (Dutch Foundation for the Code of Pharmaceutical Advertising) – Disclosure Requirements

- **Pharmaceutical Companies** will **publicly disclose** all financial relationships, including the nature and duration, with physicians and pharmacists valued at **over € 500 per year**
  - Recent discussions on the possibility of similar disclosure requirements for the **medical device industry**
  - First declaration to be made in 2013 for **payments in 2012**
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# United Kingdom

## ABPI (Association of the British Pharmaceutical Industry ) Code of Practice - Transparency Reforms

- **Pharmaceutical Companies** will have to report payments to healthcare professionals for services including:
  - Speaker Fees, Advisory Boards, Consultancy, and Sponsorship for Attendance at Meetings, Donations, Grants
- As of May 2011, pharmaceutical companies will **no longer provide branded promotional items** to healthcare professionals unless they are for a formal patient support program
- First declaration to be made in 2013 for **payments in 2012**