Advanced Issues in Global Transparency, Disclosure, Aggregate Spend and Sunshine

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Agenda

- Important definitional differences
- Reporting research and development payments
- Cross-border spend
- Master data management
- Managing vendor agreements and agreements with covered recipients

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Covered Recipients

(How to identify HCPs/HCOs/ Others for reporting?)

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Japan

Japan Pharmaceutical Manufacturers Association
Code of Practice & Transparency Guidelines

- Healthcare professionals
- Healthcare service providers
- Healthcare-related personnel
- Patient Organizations

JPMA

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Australia

Medicines Australia Code of Conduct

- Healthcare professional consultant
- Healthcare professions and healthcare professionals
- Health consumer organisations

MEDICINES Australia

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United States

"Covered Recipients"

- Physicians

  Except for a physician who is a *bona fide* employee of the applicable manufacturer that is reporting the payment.

- Teaching Hospitals

  List published annually by the Centers for Medicare & Medicaid Services.

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- Healthcare Organisations
- Healthcare Professionals
- Patient Organisations

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France

- Healthcare professionals;
- Associations of healthcare professionals and associations of students for relevant occupations;
- Students for relevant occupations;
- User associations of the health system (public or private);
- Health facilities;
- Foundations, learned societies, and consulting companies or organisations in the health sector;
- Publishing companies: press, radio, television, and on-line media;
- Editors of prescription and dispensing software; and
- Legal entities contributing to the initial training of healthcare professionals.

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Transfer of Value

(What is Reportable? How is it tracked?)

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What is Reportable? Japan

- Research and development expenses
- Academic research support expenses
- Manuscript and writing fees
- Information provision-related expenses

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What is Reportable? Australia (current)

- Payments for consulting services and serving on advisory boards
- Educational meetings and symposia
- Market research
- Relationships with health consumer organisations

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What is Reportable? "Transfers of Value" United States

- A transfer of anything of value (e.g., reprints, publication support)
- Ownership or investment interest held by a physician or his/her immediate family.

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What is Reportable? "Transfers of Value" EFPIA

"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."

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What is Reportable? France

- Companies must disclose the existence of agreements with and benefits provided to recipients.

Reporting Research Payments

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Reporting Research Payments Japan

- Research and development expenses must be disclosed including expenses of clinical studies, clinical trials for new drugs and post-marketing clinical studies conducted under public regulations.

JPMA

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Reporting Research Payments Australia

- Payment in relation to research and development work, including conducting clinical trials, are not included in the disclosure requirement.
- However, the Medicines Australia Code requires companies to report market research payments including disclosure of total fees and expenses.

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Reporting Research Payments U.S. Sunshine Act

- Payments made in connection with research that are subject to a written agreement OR research protocol are subject to special reporting requirements.
- Includes payments and transfers of value related to pre-clinical, phases I through IV clinical studies, and investigator-initiated research.

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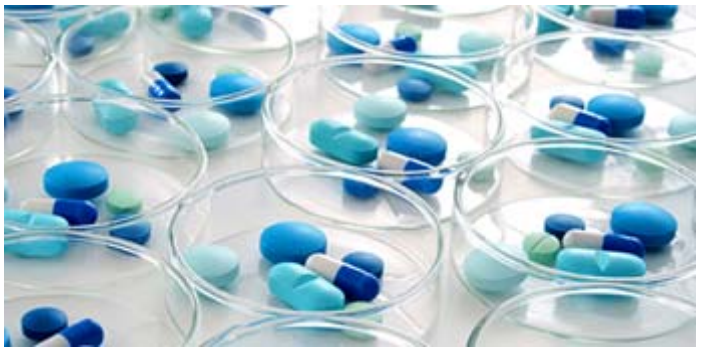
Reporting Research
EFPIA

- Research & Development
  - Transfers of value to HCPs/HCOs related to the planning and conduct of:
    - Non-clinical studies
    - Clinical trials
    - Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study



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Cross-Border Spend

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Case Studies

- **Case study # 1:** Australian doctor conducts research in Australia on behalf of a US applicable manufacturer.
  - *Reportable under the US Sunshine Act/Medicines Australia?*
- **Case study # 2:** Australian physician practicing in Sydney who is licensed in Australia and New York conducts research in Australia on behalf of a US applicable manufacturer.
  - *Reportable under the US Sunshine/Medicines Australia?*

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Disclosure FAQs

January 2014

Question (Section 2.05) *(Batch 1 Q.15)*: **When a consultant is used in another country, where should this be disclosed?**

Answer: Transfers of Value to a HCP / HCO whose practice, professional address or place of incorporation is in Europe, are required to be disclosed in the country where the **Recipient has its principal practice**, pursuant to the national code of the country where the Recipient's principle practice is located, whether the Transfers of Value occur in or outside that country.

- The Code requires transparency of Transfers of Value based on the country of primary/principal practice, which will ensure that the searching patient or other interested stakeholder can easily find this information. The physical address where the HCP practices or HCO is located should be used as the reference when determining in which country the data should be disclosed.
- Each Member Company will clarify in its Methodological Note how cross-border Transfers of Value are being disclosed.
- Examples:
  - A Member Company's US headquarters sponsoring a HCP whose practice is in Sweden for an activity in Germany will be required to disclose the Transfer of Value under the name of the Recipient HCP in Sweden (following the applicable laws, regulations and the national code in Sweden)
  - An Italian Member Company sponsoring a HCO located in Italy to provide expertise to a hospital in Tunisia will be required to disclose the Transfer of Value in the name of the Recipient HCO in Italy (following the application of Italian laws, regulations and national codes in Italy)
  - A Spanish Member Company sponsoring a US expert for participation in an advisory board in Argentina is not required to disclose that Transfer of Value under the EFPIA Code. However, disclosure may be required in other jurisdictions, including in the US under the "Sunshine Act".

Disclosure FAQs

January 2014

Question (Section 2.05) *(Batch 2 Q.8)****:*** **A US affiliate of a company that is an EFPIA direct member makes a Transfer of Value to a (Spanish) HCP. Is it understood that this Transfer of Value has to be captured according to the (Spanish) Code, and the (Spanish) affiliate, if any – not the US one – would be responsible for reporting the Transfer of Value? Which entity would be sanctioned?**

Answer: Disclosures shall be made pursuant to the national code of the country where the Recipient has its principal practice. Unless the platform for disclosure is fixed in the national code or imposed by national law, the Member Company will decide whether the disclosure will be made on the companies head office website or each affiliates website. But it must be possible for the public to easily find and access the disclosed information in the country where the Recipient has its principal practice.

- In case the Member Company is found in breach of the applicable code, the Member Association of the country where the Recipient has its principal practice, in this instance Spain, would sanction the Spanish company as this is within their jurisdiction.
- For example, in the UK it is a clearly established principle that the UK Company is responsible under the ABPI Code for the activities of overseas companies in the UK.

Cross-Border Challenges

- Extraterritorial reach of disclosure codes
- Data privacy considerations
  - How to maintain data?
  - Safeguard requirements
  - Obtaining consent
- Data captured accurately and completely
- Integrating systems and customer master

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Master Data Management
(Data Quality)

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Maintaining Data Quality

Challenges

- **Unique identifier** for HCP/HCO needed to consolidate transfer of values per recipient per year.
  - Ideally, one common global database to be established also for cross-border transactions.
  - Data privacy aspects to be considered when the database is setup.
- **No common definition of HCP**
  - Detailed information about sub-type of recipient needed in the database.
- **No common list of expense details**
  - Broad data capture requirements for every expense
- **Conclusion**
  - Definition of HCP needs to be done on country level to respect different interpretations.
  - Pragmatic solution needed to collect consent for disclosure of transfer of values from all external partners even without being seen as a HCP in all countries. Detailed expense records must be maintained to comply with different reporting requirements/formats.

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Maintaining Data Quality

- **Even the best data capture processes may result in data gaps, particularly regarding HCP data**
  - How will your team address those data gaps?
    - What is your preferred data source?
    - When will gaps be identified and addressed?
    - Who will remedy those gaps?
    - Who will approve the remedy selected?
    - Where will the data be remedied? E.g., in a source system or in a reporting solution?
  - How do you document this process?

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Developing a Customer Master

- A unique identifier is required for data integrity and to aggregate all spend data to the appropriate recipient
- Customer master data must be reviewed to avoid duplicate entries
- Customer master records must contain the necessary data required for local, national, and international compliance reporting
- To ensure data integrity, modifications to existing records and creation of new records must follow company standard operating procedures

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Master Data Management
(Privacy Considerations)

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Consent to Disclose

When is it needed?

Factors to consider when determining whether the recipient's privacy protection(s) requires that consent be obtained prior to disclosing data:

- Citizenship of recipient
- Location of recipient
- Location of spend

Consent process and content will be different depending on the local regulation (transparency and/or data privacy regulations).

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Collection of Consent to Disclose Transfers of Value

Following data privacy regulations, personal related data should be kept confidential. However, the **following justifications allow** the required disclosure:

- Unambiguous consent (but revocable).
- Legitimate interests of the company to disclose the data.
- Compliance with legal obligation (e.g., in France or Portugal) but will not extend to self-regulatory Code (e.g., EFPIA-> **thus, consent is needed)**.

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Collection of Consent to Disclose Transfers of Value

Different approaches for collecting consent from HCP/HCO with respect to disclosure requirements

Option 1: Consent by Activity

- Consent is collected with each contract / invitation to a meeting
- Country specific clause to be used (country of recipient)
- If consent is not given for all activities per individual, the person should be treated as "non-consenting recipient" (for disclosures under EFPIA, this individual would be disclosed in the aggregate amount)
- Every activity needs to be tracked and consent status to be evaluated before disclosure of data

Option 2: Consent by Individual

- Consent is collected by individual person or institution and separately from contract
- Documentation in the database (yes/no) and ideally together with the consent sheet
- Only one consent needed for all transfer of values
- Process to be set up to repeat the consent (e.g. biannually)
- Maintenance of data by country of recipient

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Collection of Consent to Disclose Transfers of Value

Challenges

- How to convince HCP to provide the consent for disclosure?
- How to manage, technically, the clear identification of the "consent status"?
- Resources needed to manage this process to ensure correct reporting.
- How to handle revocation of HCP consent?
- Robust process and clear responsibilities to be defined to avoid data privacy violations.

The Key: Require HCP consent for disclosure in contract

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Beyond Data Capture

- Managing Vendor Agreements
- Managing Agreements with Covered Recipients

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Evaluate Language Within Vendor Contracts

- **Do vendors know what data to provide, the proper format and your requirements?**
  - How are you communicating with your vendors?

- **Certain vendors should have their role in your reporting process spelled out in detail in an agreement, work order or scope of services (e.g., Speaker Program vendor).**

- **If your vendors interact with physicians on your behalf, do you want them addressing your reporting requirements?**
  - If so, what are they saying? This should be spelled out in an agreement, work order, or scope of service.

Sample Consent Language for HCP Contracts

Healthcare professional ("HCP") acknowledges and agrees that ABC Pharma reserves the right to disclose, as appropriate and necessary under all applicable laws and regulations, or otherwise deemed necessary by ABC Pharma: (1) the existence and nature of HCP's relationship with ABC Pharma; (2) the actual services rendered by HCP; and (3) direct and indirect payments, transfers of value, and other compensation, royalties, licenses, and ownership or investment interests provided to HCP by ABC Pharma. By acknowledging and agreeing that ABC Pharma reserves the right to disclose such information, HCP consents to ABC Pharma capturing, maintaining, and disclosing data pertaining to the HCP.

Beyond Data Capture
Develop Sustainable Training Efforts

- **What is the scope of your company's training efforts?**

- **Who will be trained?**
  - Value in training all vs. value in training some

- **What will be covered?**
  - Laws?
  - Nuances?
  - Processes/policies/procedures?

- **How frequently will training occur?**

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Beyond Data Capture
Ensure Effective Monitoring and Periodic Audits

- What is acceptable scope for your company?
- What methodology will you employ?
- What can be audited?
  - Data
  - Vendor data
  - Capture process
  - Remediation process
  - Reporting process
  - Sign-off/attestation process
  - Training records

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Thank you for attending today's session

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