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Cross-Border HCP Engagements

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Cross-border HCP engagements: Examples - 1

Congress Sponsorship

Speaker Engagements

Consultancy Agreements

Symposia

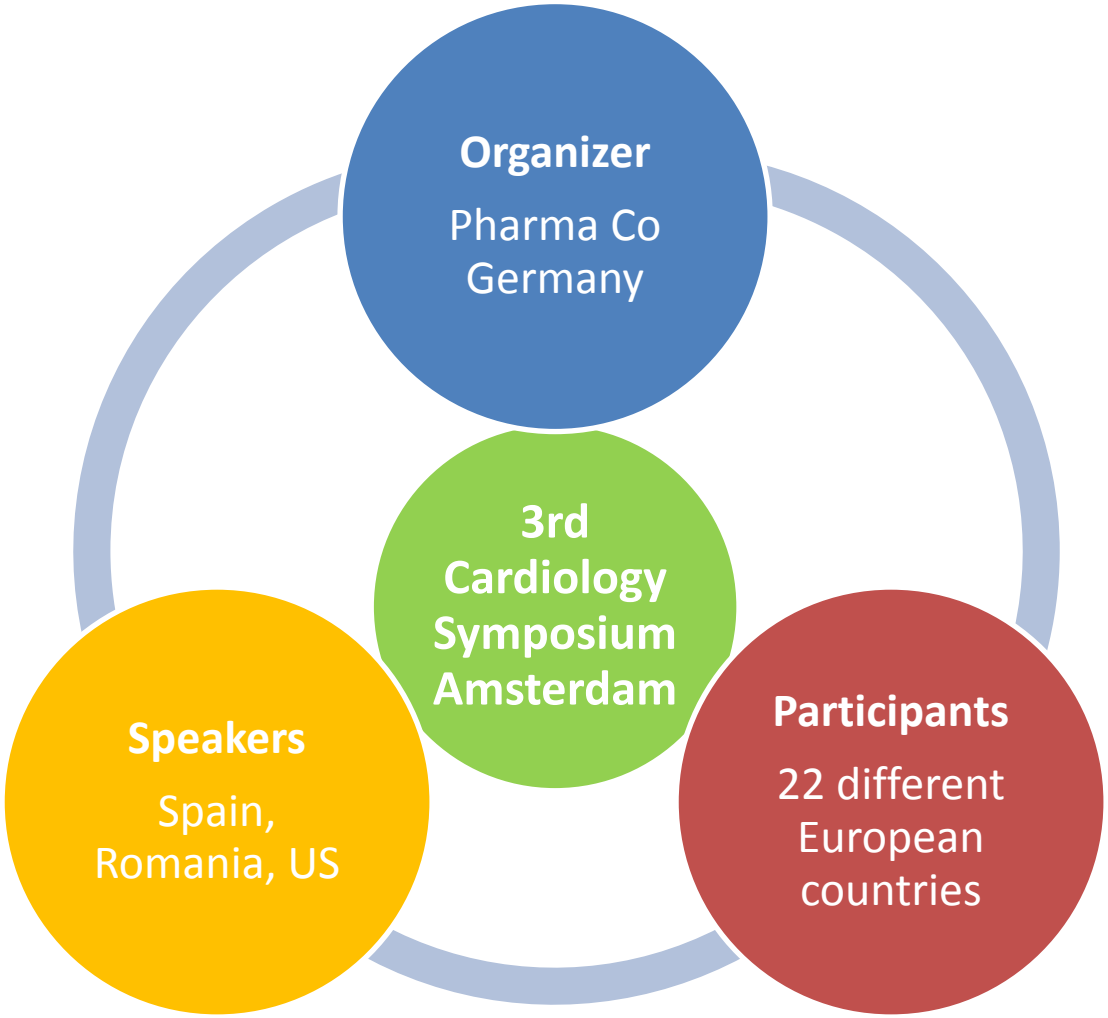
Educational Meetings

Investigator Meetings

Advisory Boards

Hospitality and travel

Cross-border HCP engagements: Examples - 2



HCP Engagements Compliance Framework

Industry Codices

- IFPMA
- EFPIA
- National Codices

Laws & Regulations

- EU LAW
- National Laws
- Cross-border applicable laws: e.g. UK Bribery Act, FCPA, US Sunshine Act

Internal Rules

- Global
- Regional
- Local

Applicable local rules for cross-border HCP engagements

Organizer's Country

- Legitimate purpose/admissibility of the interaction/agenda
- **Location, venue, accommodation, hospitality, items of medical utility/educational materials**

HCP Home Country

- **Fair market value (FMV)**
- Legitimate purpose/admissibility of the interaction/agenda
- Notifications and/or **approvals required** (e.g. of the employer)
- **Location, venue, travel, accommodation, hospitality, items of medical utility/educational materials**
- Data Privacy
- Informational and promotional materials

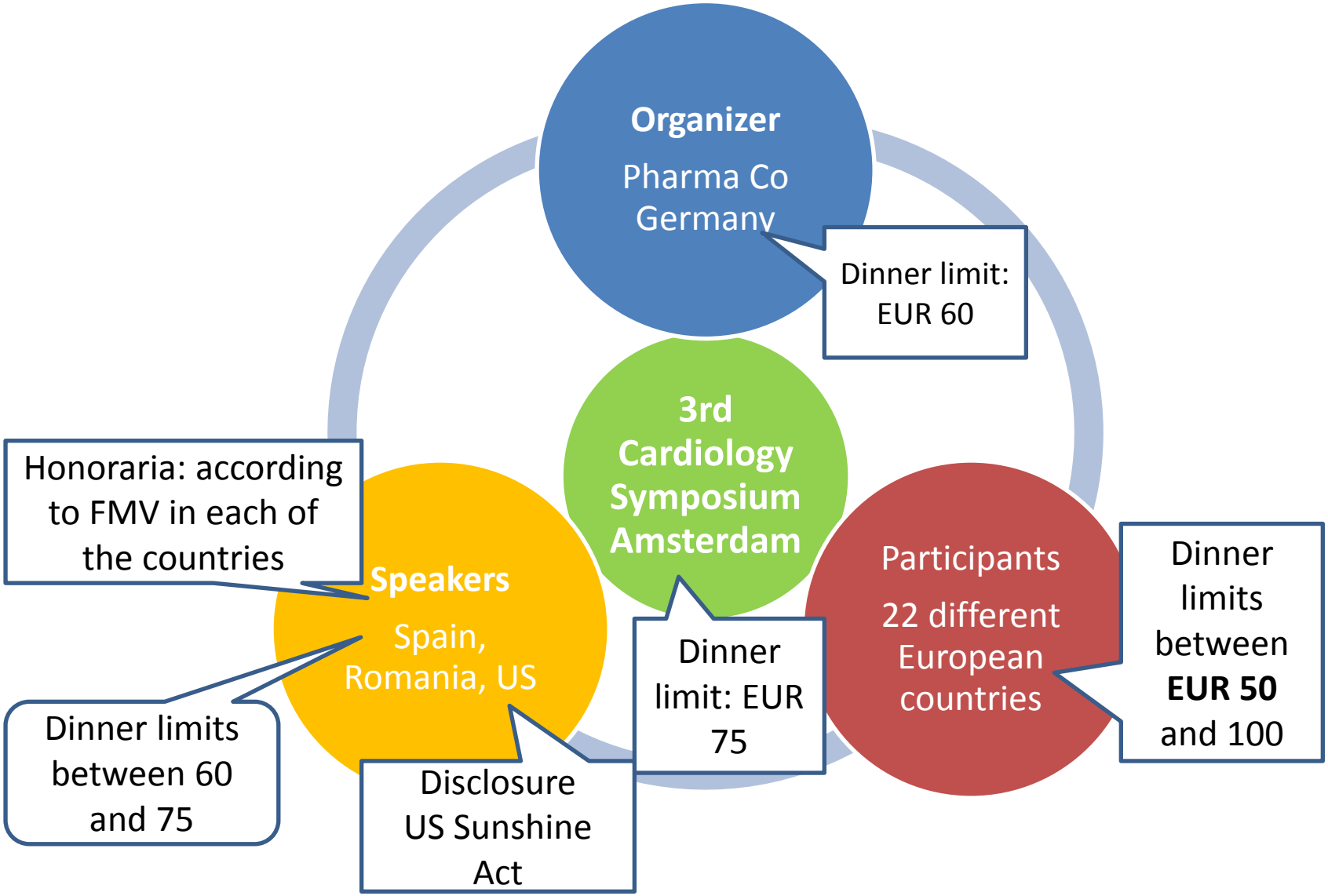
Event Country

- **Venue, accommodation, hospitality limits**
- Agenda, informational and promotional materials (for own events/materials)

In case of doubt the stricter rules prevail!

In case of FMV for honoraria/fees the rules in the HCP's home country prevail!

Cross-border HCP engagements: Applicable rules example



Managing cross-border HCP engagements - 1

- Define on global or at least regional level the main **criteria** for cross-border engagements by reflecting the IFPMA and EFPIA principles:
  - Type of engagements
  - Scientific programme requirements
  - Venue, travel, accommodation, hospitality
  - Informational and educational materials/items of medical utility
  - Expert selection/FMV
  - Contracting
- Define **approval process** and responsibilities:
  - FMV/honorarium approval by Compliance Officer in HCPs home country
  - Ensure compliance with any stricter rules in the countries involved
- Pre-approved **limits for travel, accommodation, hospitality**, educational materials and items of medical utility in the different countries

Managing cross-border HCP engagements - 2

- Integrate approval process and spend collection for ensuring compliance with disclosure obligations into automated **IT tool/system**
- Standardized **Contractual Templates**:
  - local adaption where mandatory necessary
- Enhanced **planning**
  - allow sufficient time for obtaining approvals and contracting
- **Communication and awareness**

Third parties in cross-border HCP engagements

- Pharmaceutical companies are responsible for compliance, even if the HCP engagement is not made directly but via third party, e.g.:
  - Medical Societies
  - Congress Organizers
  - Event/Travel Agencies
- Ensure compliance by third parties:
  - Contractual obligation
  - Clear communication of compliance requirements

EFPIA E4ETHICS TOOL FOR THE ASSESSMENT OF INTERNATIONAL EVENTS IN EUROPE

Assessment of major international events taking place in Europe (at least 5 countries/more than 1000 participants)

Assessment criteria:

- Scientific Programme Schedule/Structure
- Location and Venue
- Hospitality/Entertainment
- Other Activities
- Accompanying Persons

http://www.efpia-e4ethics.eu

Thank you for your attention!