

Japan's New Payment Disclosure Guidelines

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JPMA Guidelines Overview



- January 2011, JPMA approved Transparency Guidelines
 - Voluntary guidelines, not law
- All JPMA members committed to comply with Guidelines
- Disclose all payments to HCPs made on/after January 1, 2012
- First disclosure (of 2012 payments) in 2013
- Each company to disclose payments on its own website

Payment Categories

Payment Category	Disclosure Method
R&D, Studies & Post-marketing Studies	Aggregate Annual Amount
Speaker Programs, etc.	Aggregate Annual Amount
Dining, Entertainment, Gifts	Aggregate Annual Amount
Donations	Annual Amount per Recipient
Honoraria (speaker/advisor)	Annual Amount per Recipient

- Includes indirect payments (e.g., through CRO or meeting vendor)
- JPMA issued several Q&A, but further details are up to the discretion of each company to decide

Further Details re Categories

Categories	Disclosure Items	Level of Disclosure		
A. Research and Development	Joint research funding	Annual total		
	Contract research expenses	Annual total		
	Clinical trial	Annual total		
	Post-marketing clinical trials	Annual total		
	Infection case reports adverse costs	Annual total		
	Post-marketing surveillance	Annual total		
B. Academic research grants	Scholarship donation	University & Department	Number of Donations	Yen
	General Donations	University/Foundation	Number of Donations	Yen
	Academic Society Donations	Name of Academic Society Meeting/Regional Mtg/ Study Group Mtg		Yen
	Cost for Society co-sponsored event (conference)	Name of Academic Society Meeting & Seminar		Yen
C. Honoraria (speaker, advisor, consultant)	Lecture fee	Professor/Director, Department, & University/Hospital	Number of services	Yen
	Manuscript writing fee/ supervising fee			
	Consulting commission			
D. Meetings & Events; Information Provision	Lectures (co-organizer) meeting expenses	Annual # of meetings	Annual Total	
	Explanation meeting expenses			
	Medical and pharmaceutical books, supplies, etc	Annual Total		
E. Meals, Entertainment, Gifts, Other Payments	All payments to HCPs not included in other categories	Annual Total		

Some Points of Comparison: US Sunshine Act & Japan Transparency Guideline

- Scope of transactions covered
- Transfer of value vs payment
- Level of detail of disclosure
- US: “teaching hospitals”
- Submission of each transaction to US Govt

Initial Idea vs Current Model

March 31 draft:

- Similar to US Sunshine Act
- 3 phase implementation over 3 years, starting with only aggregate amounts and eventually ending with individual-level disclosure of all payments above ¥5,000
- Types of Payments Covered:
 - Clinical Trials, Post-marketing Studies
 - Honoraria to Individual HCPs
 - Donations
 - Meals, Entertainment & Gifts
 - Seminars & Study Meetings (including hospitality)

May 19 (and later) drafts:

- Essentially the same categories
- Debate over whether to include Meals/Entertainment/Gifts as separate category, or include in Seminar/Meeting category (with hospitality)
- Dropped individual disclosure for all categories except Donations and Honoraria; shift to aggregate annual amount—most importantly for Meals/Entertainment/Gifts

Discussion Issues

- Competition Laws
 - Voluntary guidelines; common standards, alignment and information sharing subject to Competition Laws
 - Alignment would be helpful on disclosure timing, details of what/how to disclose, how to deal with privacy (below), etc.
 - Guidelines do not spell out every detail, including common date to start disclosure—who wants to go first?
- HCP Right to Privacy
 - Individual disclosure of honoraria and donations subject to privacy laws—**HCP consent required**
 - Should desire for transparency trump right to privacy? Should companies refuse to work with HCPs who do not consent?
 - What if a critical thought leader says “no”?
 - Legal limits on industry agreement to refuse to deal